DISSERTATION ON
"A COMPARATIVE STUDY OF USING COLLAGEN PATCH OR FAT PLUG IN MYRINGOPLASTY FOR SMALL TYMPANIC MEMBRANE PERFORATIONS"

Dissertation submitted in partial fulfillment
of the regulations for the award of the degree of

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CERTIFICATE

This is to certify that this dissertation **"A COMPARATIVE STUDY OF USING COLLAGEN PATCH OR FAT PLUG IN MYRINGOPLASTY FOR SMALL TYMPANIC MEMBRANE PERFORATIONS"** submitted by Dr.AJAIY.M, appearing for M.S ENT Branch IV Degree examination in April 2016 is a bonafide record of work done by him under my direct guidance and supervision in partial fulfillment of the regulations of the Tamilnadu Dr.M.G.R Medical University, Chennai. I forward this to the Tamilnadu Dr.M.G.R Medical University, Chennai, Tamilnadu, India.

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DECLARATION

I, **DR.M.AJAIY**, solemnly declare that this dissertation entitled **"A COMPARATIVE STUDY OF USING COLLAGEN PATCH OR FAT PLUG IN MYRINGOPLASTY FOR SMALL TYMPANIC MEMBRANE PERFORATIONS"** is a bonafide work done by me in Upgrade Institute Of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi General Hospital, Chennai during the period of 2013 to 2016 under the guidance of **Prof.Dr.G.SANKARANARAYANAN, M.S.D.L.O., DNB., MNAMS.,** Professor, Institute Of Otorhinolaryngology, Madras Medical College and Rajiv Gandhi General Hospital, Chennai – 3 and submitted to The Tamilnadu Dr.M.G.R. Medical University, Guindy, Chennai – 32 in the partial fulfillment of the regulations for the award of the M.S.E.N.T ., (Branch IV).

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INDEX

INTRODUCTION

- One of the most common problems in otorhinolaryngology is perforation of tympanic membrane.

- Hearing loss, middle ear infection, persistent otorrhoea and acquired cholesteatoma are the main problems resulting when left untreated.

- Although many small perforations heal spontaneously over time, some may remain persistent due to infection or some other causes.

- Down the century many graft materials have been used with varying success rates.

- Graft materials like muscle fascia, perichondrium, vein grafts, cartilage, fat, alloderm , xenografts like porcine small intestine submucosa, and biomaterials like paper patch, gelfoam and hyaluronic acid derivatives, genetically engineered biomaterials like silk fibroin, calcium alginate, chitosan and collagen have been tried.

- Yet conventional temporalis fascia graft has been proven to be the most effective graft material used for tympanic membrane perforation closure with high success rate and very less re-perforation rates.

- This study was designed to find out the efficacy of **collagen patch** over the **fat plug myringoplasty** technique in the treatment of small tympanic membrane perforations.

- In this prospective study we have compared the success rates , rate of healing and hearing improvement between the fat plug myringoplasty and collagen patch technique which were done as the **office procedures.**

- We have tried to determine the role of etiology in their success rates and causes determining the failure of the procedure.

EMBRYOLOGY OF TYMPANIC MEMBRANE

- The development of tympanic membrane starts by 4th week of intrauterine life.

- A funnel shaped ectoblastic pouch grows inwards from 1st branchial cleft.

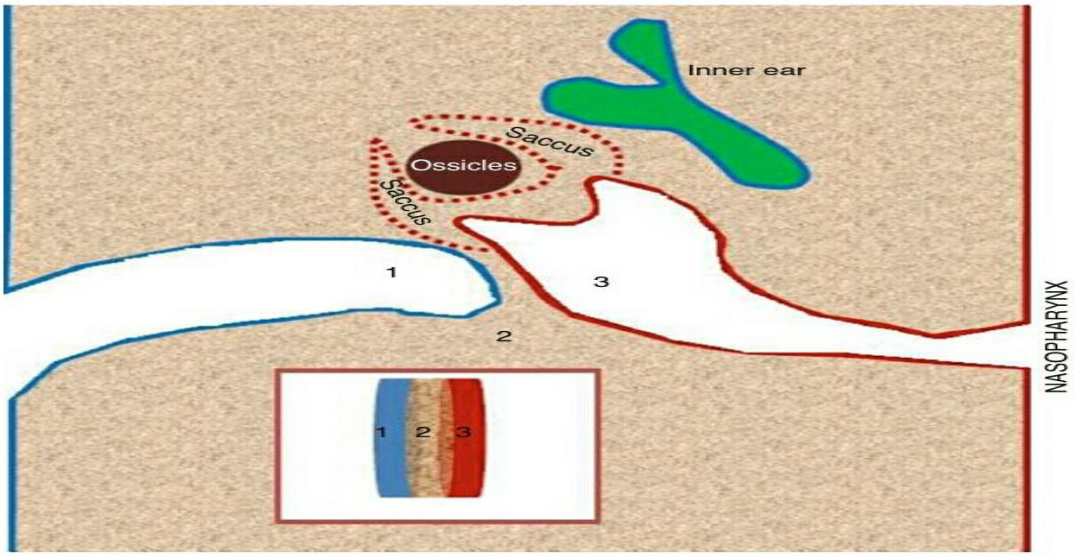
- It grows till it reaches the endoblastic pouch from 1st branchial pouch.

- 5th week of intrauterine life-due to flexion-extension position of the embryo mesenchyme interposes between the above said pouches.

- 8th week of intrauterine life-epithelial cells at the bottom of ectoblastic pouch proliferate and form a epithelial plate reaching the endoblast.

- When the tympanic membrane appears it already has 3 layers with horizontal diameter of 2mm.

- At birth tympanic membrane is in horizontal plane. As the tympanic ring changes its orientation the tympanic membrane becomes vertical.



ANATOMY OF THE TYMPANIC MEMBRANE

- The tympanic membrane separates the external auditory canal from the middle ear.
- **It is semi-transparent with dimensions of 8mm width, 9-10mm high and 0.1mm thick.**
- **Umbo** is the zone in the tympanic membrane where the handle of malleus is attached to central part of inner surface and draws it centrally.
- The tympanic membrane is divided into upper-pars flaccida and lower-pars tensa.
- The **pars tensa** is the larger part and it is a fibro-cartilagenous framework which is thickened peripherally to form the tympanic annulus which snuggly fits into the tympanic sulcus.

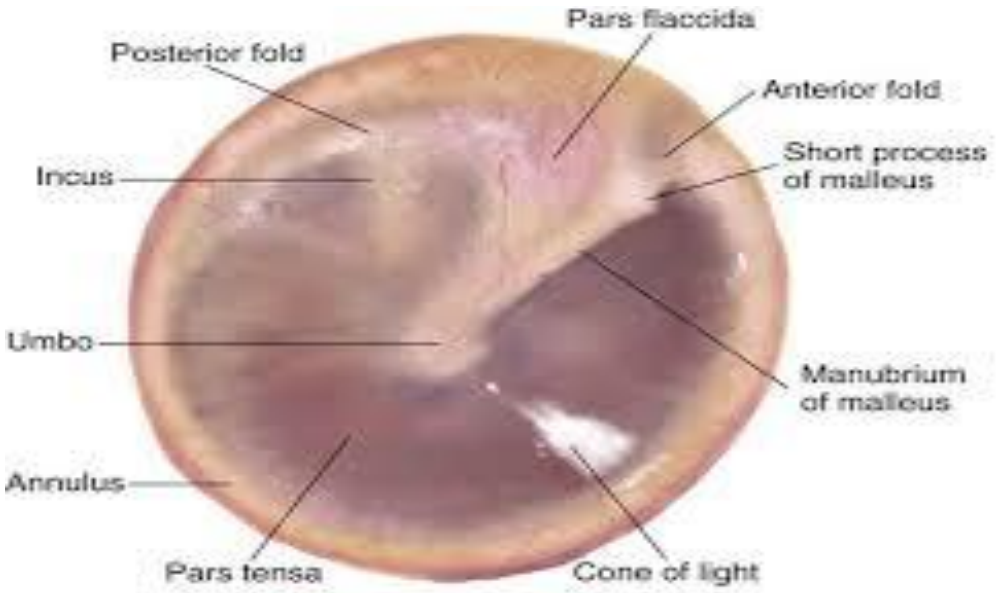
- The **pars flaccida** is also known as Sharpnell's membrane occupies the notch of Rivinus and is attached to the scutum.

TYMPANIC SULCUS

- It lodges the annulus of the tympanic membrane.
- Average depth of the sulcus is 1mm.The posterosuperior part of the sulcus is shallow and is 4mm deep.

TYMPANIC SPINES

- There are two spines present at the junction of tympanic ring and the outer attic wall.
- *Anterior tympanic spine*: present at the antero superior end of tympanic ring.this forms the anterior limit of the notch of Rivinus.
- *Posterior tympanic spine*: present at the postero-superior end of the tympanic ring. This forms the posterior limit of notch of Rivinus.



TYMPANIC MEMBRANE

TYMPANIC CANALICULI

The inner surface of the tympanic ring near the spines has 3 openings

- ***Glasserian fissure or the petrotympanic fissure:*** opens just anterior to the tympanic membrane. This fissure receives the anterior malleal ligament and transmits the anterior tympanic artery.

- ***Canal of Huguier or the Iter Chordae Anterius:*** located in the medial end of the petrotympanic fissure.Chorda tympanic nerve exits via this canal and reaches the infratemporal fossa.

- ***The Iter Chordae Posterius:*** situated medial to posterior tympanic spine.Chorda tympani nerve exits this via this canal to reach the tympanic cavity.

TYMPANIC ANNULUS

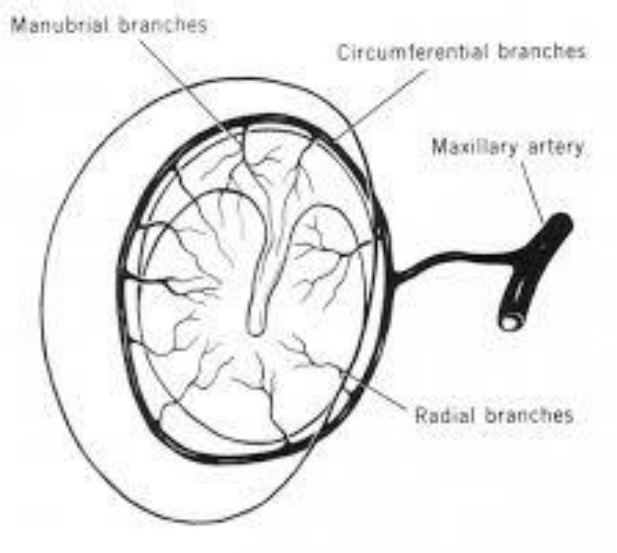
- It is also known as the *Gerlach's ligament*.

- It is a fibro catilagenous structure that maintains the insertion of tympanic membrane into the sulcus.

- At the level of the tympanic spines the annulus prolongs towards the lateral process of the malleus forming the anterior and posterior tympanomalleal strands.

- Medially these strands form slight ridges of mucous membrane on the inner side of the tympanic membrane-anterior and posterior tympanomalleal folds.

BLOOD SUPPLY OF THE TYMPANIC MEMBRANE



BLOOD SUPPLY

- Inner surface, Outer surface
- Anterior tympanic artery, Arteria manubrii
- Stylomastoid branch from posterior auricular artery

NERVE SUPPLY OF THE TYMPANIC MEMBRANE

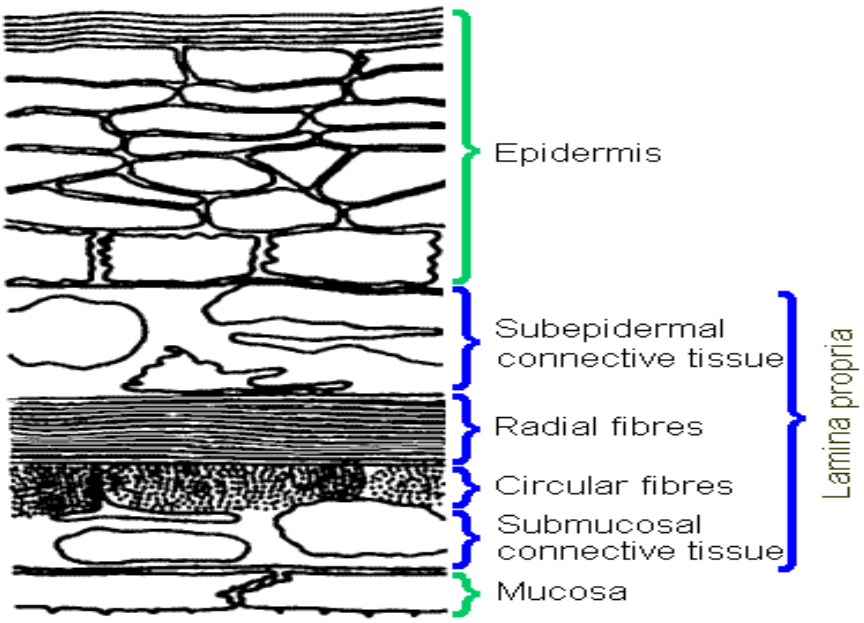
- The medial surface of the tympanic membrane is supplied by the tympanic plexus
- The lateral surface is supplied by the auriculotemporal nerve a branch of the mandibular division of the trigeminal nerve and also by the auricular branch of the vagus nerve also known as the Arnold's nerve or the Alderman's nerve.

MICROSCOPIC STRUCTURE OF THE TYMPANIC MEMBRANE

- Even though the pars tensa and pars flaccida are made up of three layers the both differ in structre.

THREE LAYERS OF THE TYMPANIC MEMBRANE

- Lateral epidermal layer
- Medial mucosal layer
- Middle layer or lamina propria



EPDIERMAL LAYER

- The epidermis of the tympanic membrane and the bony external auditory canal is specialized in a way that it does not contain any glands or hair follicles and
- It has the ability of lateral migration which is not found in other places.

- ❖ This accounts for the self cleansing ability the ear canal.

MUCOSAL LAYER

It is a continuation of the mucosal lining of the middle ear cavity

LAMINA PROPRIA

This layer consists of fibrous tissue.The amount and organization of this layer is the main difference between pars tensa and pars flaccida.

PARS TENSA

The fibrous layer is attached to the handle of malleus and to the tympanic bone and consists of two layers of collagenous fibres oriented radially and circularly.

Radial fibrous layer: also known as the Stratum Radiatum,it radiates outwards to the annulus from the ,manubrium

Circular fibrous layer: also known as the Stratum Circulare,is medial to the radial layer and the fibres here are arranged concentrically and is inserted on the manubrium .

PARS FLACCIDA

The lamina propria of sharpnell's membrane is composed of small amount of elastic and collagenous fibres with no special arrangement and gradually inserts into dermis of the meatal skin.

COLLAGEN STRUCTURE OF TM

COLLAGEN

- "Collagens are the most abundant proteins of the body and they are major components of connective tissue".

- "The collagen molecule is made up of 3 polypeptide chains, called **α-chains,** that are twisted around each other, forming a long, stiff, triple-stranded helical structure stabilized by the small amino acids proline and glycine."

- "These **triple-stranded helical** structures together form collagen fibrils that are about **10 to 300 nm** in diameter".

- "The collagen fibrils group together to form collagen fibres which are several micrometers in diameter and thus visible under electron microscope".

- "About 25 different α-chains have been described, each encoded by separate genes and forming about **20** different collagen types, which are characteristic of different tissues".

- Different tissues have different patterns of collagen fibre arrangement with different diameters.

- "**Type I collagen** is the main collagen of bone, skin, tendon, and newly healed wounds".

- "**Type II collagen** is thinner and is the typical collagen of cartilage".

- "**Type III collagen** is found to a great extent in embryonic tissue, healing wounds, and the connective tissue of the skin, blood vessels, uterus, lung, and liver".

COLLAGEN IN NORMAL TYMPANIC MEMBRANE

- The TM consists of 2 parts: the pars tensa and the pars flaccida.
- The outer lining of the pars tensa is made up of keratinizing epithelium.
- **"The middle layer is composed of radiating and circular collagen fibers, and these make up a stiff structure"**.
- The inner layer facing the middle ear is a single-layered epithelium.
- Between the inner and outer epithelial layers of the pars tensa lies a loosely arranged connective tissue layer.
- " In the pars flaccida , connective tissue layer is thicker and has a much looser structure when compared to the pars tensa".
- The connective tissue of sharpnell's membrane has abundant vessels, nerve endings and mast cells.
- "The collagen fibers are thicker compared with those of the pars tensa and are organized not as a flat layer only but rather in 3 dimensions".
- "The fibers were small, with a quadrangular cut surface and lack the typical periodicity of collagen fibers which proves that collagen fibres in the TM have special type of arrangement and structure".

- “The collagen fiber structure of the annulus and at the manubrium was continuous with and similar to that of the lamina propria of the TM”.
- However, very little is known about the specific types of collagens that constitute the TM.
- TM has been found to constitute **type I,II,III,IV,VI** of collagen fibres.
- “The annulus and the lamina propria of the healthy TM consists of type II collagen”
- The lamina propria of pars tensa is very thin yet strong.
- The sharpnell’s membrane is found to be thicker and yet more elastic.
- “The pars tensa and pars flaccida differ in their structure, elasticity and strength and thus have different roles in physiology of middle ear and in hearing mechanisms”.
- “The collagen of the pars tensa and the pars flaccida not only differs structurally in thickness and organization but also in the biochemical composition of collagen types”.
- Type II collagen mainly constitutes the connective tissue layer of pars tensa.
- Type II collagen is found in cartilages and thus it is thought to provide **stiffness** and hence reinforcement to pars tensa.
- “The pars tensa is very thin yet stiff, with low elasticity, which may be optimal for its function in hearing because of its high sensitivity to

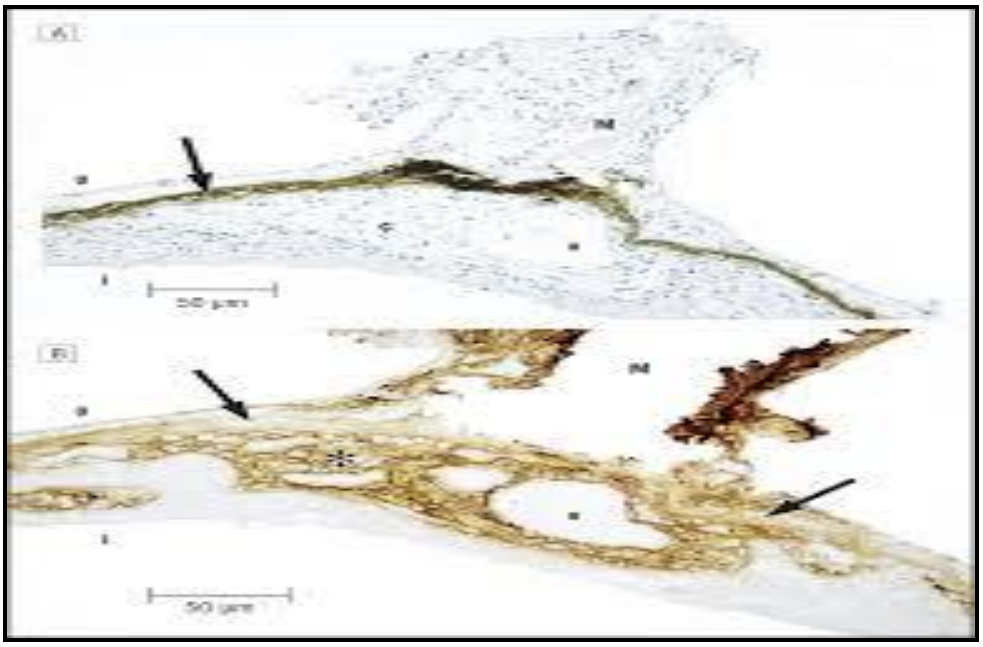
sound vibrations and effective transfer of vibrations to the malleus handle".

- "In the tympanic membrane, collagen types I and III were not found within the main collagen layer but found in the thin layer of loose connective tissue of the pars tensa".

- Furthermore, collagen types I and III were found at the insertion of the pars tensa at the handle of malleus and around blood vessels.

- Type I collagen is also found in the connective tissue of the pars flaccida.

- "Type III collagen is found in extensible tissues, and therefore we would expect to find it in the pars flaccida, which is an elastic tissue, but type III collagen was not found in the healthy pars flaccida but was found in the pars flaccida during infection".



COLLAGEN IN PERFORATED OR DISEASED TM

- "In experimental perforation of the TM in animal models, the epithelial layer soon starts to proliferate over the defect in the direction of epithelial migration of the TM, supported by an underlying bed of inflamed connective tissue".

- "The perforations close within 12 days".

- Little is known about the effect of infection on the collagen layer of the TM.

- The collagen fibres become thicker and are arranged in an unordered manner when the tympanic membrane ruptures.

- "During the healing phase, fibroblasts migrate and proliferate in the wound, producing an extracellular matrix rich in collagen types I and III, fibronectin, and proteoglycans".

- Cell-to-cell interaction among fibroblasts and inflammatory cells lead to the release of growth factors and neurotransmitters into the extracellular matrix.

- "This activity is initiated by The newly formed tissue is dynamically modulated by synthetic and degrading enzymes to achieve optimal function of the tissue; this process is probably enhanced by the TM being subjected to physical force".

- Type I,II,III collagen fibres are found to be present in scar tissue.

- The parallel alignment of the type II collagen has the maximal tensile strength , but when it is arranged in haphazard manner it loses its tensile property as in TM perforations.

- But however when the turnover takes place in healed TM the original type II collagen fibre arrangement is expected to happen.

- “Temporal fascia is usually used as grafting material during myringoplasty. Ultrastructural studies on temporal fascia show an irregular pattern of collagen fibrils”.

- “Immunohistochemical staining of temporal fascia has revealed type IV collagen, which is the collagen typically found in basement membranes and would most likely be found beneath the epidermal layer of the TM. but as type I collagen is typically found in fascia, we would expect to find it in the temporal fascia as well”.

- The cartilage which are used as the graft material in myringoplasty consists of type IV collagen or mixture of collagen types.

- “Engineered type II collagen grafts would be the logical choice to use during myringoplasty because the TM lamina propria consists of type II collagen”.

- “However, after the graft has served as a scaffold over which the epidermal layer can migrate and close the defect and the mesenchymal cells proliferate, the graft is thinned and possibly degraded and replaced when new collagen is produced”.

- The resulting neotympanic membrane strength and the chance for the reperforation may be dependent on the patient's healing capacity and middle ear physiology rather than on the grafting material used

- “In patients with chronic otitis media with effusion, the TM may be retracted toward the middle ear. This can result in an atelectatic TM, in which the collagen layer may be absent, resulting in loss of stability and stiffness”.

- “Immunohistological studies of biopsy specimens from patients with adhesive otitis media revealed type III collagen and, to a lesser extent, type I collagen in the granulation tissue”.

- In perforated ears and after myringotomy, collagen types I and III had already accumulated at the perforation edges by day 4, and extensive amounts of all 3 collagen types were found in the healed tympanic membrane at 3 months after myringotomy.

- The original collagen layer was embedded in the scar tissue, seemingly degenerating.

- Thus, the healed tympanic membrane consists of collagen which are not developed from the old, original collagen layer.

- “The amount of collagen types I, II, and III was increased during healing of a perforation and after infection, which could indicate that there is an increased production of these collagens”.

- " Collagen types I and III were induced at an early stage of healing, and type II appeared later, indicating that types I and III are involved in the initial stage of healing".

- " In scar tissue, all 3 collagen types were extensively found, which indicates that the collagen type and organization were different compared with healthy tissue".

- Thus, the collagen organization of the TM is modified during the inflammatory stage and the healing process.

PHYSIOLOGY OF HEARING

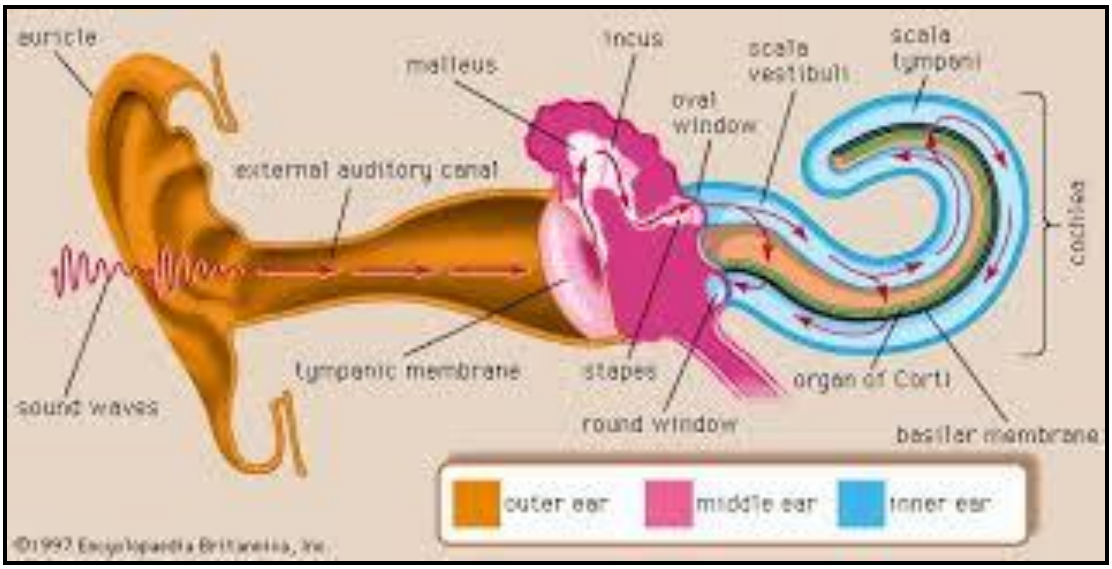
SOUND TRANSMISSION IN NORMAL EAR

- Acoustic signals are transmitted from the air in the external environment to the inner ear which is fluid filled.

- The relative impedances of the air and fluid determines the sound transmission at the air-fluid interface.

- The external and middle ear work in such a way to increase the sound pressure reaching the inner ear to match the sound conducting properties of air and cochlear fluid.

- This action is needed to overcome the loss of intensity at inner ear level as only 0.1% of the initial sound is being transmitted to the cochlear fluid.



ROLE OF TYMPANIC MEMBRANE IN HEARING

- The sound received in the external ear produces a vibratory motion in the tympanic membrane which in turn transmits the sound signals to the inner ear via the ossicular chain which totally together termed as the **TYMPANO-OSSICULAR SYSTEM** and this pathway is called as **OSSICULAR COUPLING.**

- There is another pathway in which middle ear can directly stimulate the inner ear which is termed as **ACOUSTIC COUPLING.**

- In normal ear acoustically coupled window pressure is usually 60dB less than that of ossicular coupling and hence ossicular coupling dominates in the normal ear while acoustic coupling has some role in diseased and reconstructed ears where there is compromise of ossicular coupling.

- Motion of the tympanic membrane in response to sound in the external ear creats the sound pressure in the middle ear cavity.

- Bekesey postulated that TM vibrates like a stiff plate upto 2kHz.

- The inferior part of the tympanic membrane is flaccid and hence the most mobile part of it.

- Above 6kHz the movement becomes chaotic with reduction in transfer efficiency.

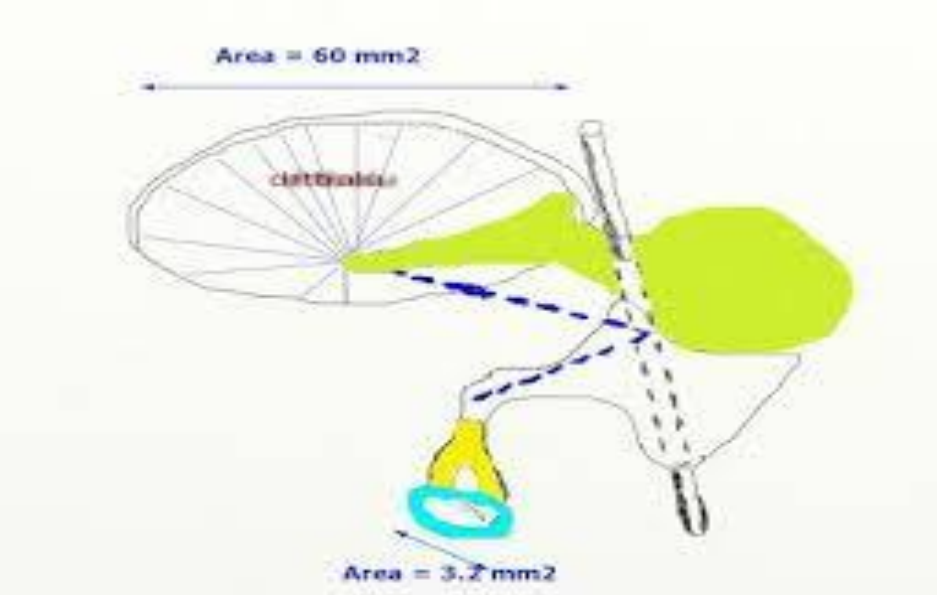
- TM buckles as it moves to and fro which reduces the malleolar movement thereby causing high pressure low displacement system and acting as the **MECHANICAL LEVER.**

- The middle ear acts like a transformer, reduces the volume velocity of the stapes relative to the volume velocity of the tympanic membrane, thereby increasing the sound pressure reaching the foot plate in relative to the sound pressure at the level of tympanic membrane.

- The major transformer in the middle ear is the ratio of the vibratory area of the tympanic membrane to that of stapes foot plate area termed as **AREAL RATIO which is 17:1.**

- Next important factor is the **LEVER RATIO which is 1.3:1.**

- So the total gain is about **22dB.**



- As described above the tympano-ossicular system increases the sound pressure at the oval window at the same time , the intact tympanic membrane reduces the sound pressure in the tympanic cavity by 10-15dB as compared to the level at the external ear.

- Thus tympanic membrane **PROTECTS** or **SHIELDS** the round window from the sound in the external ear.

TYMPANIC MEMBRANE PERFORATION AND HEARING

- Tympanic membrane perforations may cause a conductive hearing loss ranging from negligible level to 50dB.

- The loss in the sound pressure difference across the tympanic membrane leads to reduction in the ossicular coupling which is the primary mechanism leading to conductive hearing loss in perforations of the TM.

- Perforation –induced physical changes like reduction of tympanic membrane area or changes in coupling of TM motion relative to

malleus do not appear to significantly contribute to the hearing loss in perforation cases.

- Perforation cause a conductive hearing loss that depends on frequency, size of perforation and middle ear space volume.
- Perforation induced hearing loss are greatest at low frequencies and vice versa.
- Size of the perforations is one of another important factor determining the hearing loss level.
- Larger perforation results in greater hearing loss.
- Smaller middle ear space volume results in larger air-bone gaps.
- The A-B gap is often smaller in dry perforations when compared to wet and draining ear.
- The tympanic membrane perforations lead to increase in acoustic coupling by 10-20dB because of loss of shielding effect of the intact TM.
- This increase in the acoustic coupling leads to conductive hearing loss to the maximum of about 40-50dB.
- The tympanic membrane repairing procedures restores the sound protection for the round window by construction of closed air-containing middle ear cavity and rebuilding the sound-pressure transformation mechanism.

ETIOLOGY OF TYMPANIC MEMBRANE PERFORATIONS:

Tympanic membrane perforations usually result from traumatic or infectious etiologies.

INFECTIOUS ETIOLOGIES

- Tympanic membrane perforations results from acute otitis media, chronic otitis media with effusion treated with ventilating tubes, secondary to tuberculous otitis media.

- # Perforations due to acute otitis media usually heal spontaneously but rarely perforation may remain when there is associated Eustachian tube dysfunction.

- # Perforations secondary to infection by group A Beta-hemolytic streptococci has greater incidence of persistent TM perforations and mastoiditis.

- # Persistent or non-healing TM perforations, atrophy, retraction of tympanic membrane, tympanosclerosis, conductive hearing loss may result from chronic otitis media with effusion when treated with ventilating tubes.

- # Tubercular otitis media may rarely result in perforations but they are usually associated with severe hearing loss and facial nerve palsy.

TRAUMATIC ETIOLOGIES

- Penetrating trauma, non-explosive and explosive blast injuries, iatrogenic methods may lead to tympanic membrane perforations.
- Hard of hearing, tinnitus and aural fullness sometimes ear bleed might be the initial symptoms.
- Thorough otologic, audiometric and neurotologic evaluation must be done to rule out any concomitant inner ear injury, perilymphatic fistula, inverted perforated edges and presence of any displaced tympanic membrane segments in the middle ear cavity.
- Penetrating injuries are usually self-inflicted and results from ear bud trauma.
- These perforations usually heal spontaneously within 4-6 weeks.
- Other causes may be due to penetrating thermal injuries like hot slag, water activities like skiing.
- Patients suffering from TM perforations are more prone to develop otitis media.

- Non-explosive blast injuries like slapping results in sudden increase in air pressure thus perforating the TM and sometime may result in SNHL also.

- Usually these perforations heal spontaneously resulting in closure of A-B gap but SNHL doesn't revert back.

- The explosive blast injuries cause perforations that usually remains persistent due to inverted perforation edges.

- Cholesteatoma might result when segments of ruptured TM are scattered in middle ear cavity.

- The most common iatrogenic perforations are due to ventilating tubes used for treating otitis media.

- Larger size of tubes with longer retaining periods are determining factors for perforations.

- Perforations after middle ear pathologies and exploratory tympanotomy for stapedectomy are relatively rare.

THE ADVANTAGES OF FAT GRAFT

- Collapse of the grafts like in cases of underlay grafts especially at the area near the anterior annulus does not happen with Fat graft as it does not need support from the middle ear side.

- Technical operative points during fat grafting such as “graft size in the perforation, degree of lateral bulge of the fat plug and moistening of the lateral side of the graft” are also considered to be important factors of success in the fat grafting procedure.

- Fat is an active material containing angiogenic and survival factors like prostaglandins, Monobutyrin, cytokines , interleukins 1 and 6 and tumour necrosis factor which stimulate restoration and repair of the fibrous layer and promote healing and there by closure of perforations.

- These factors also provide **revascularization** which is essential for survival of the free flap.

- Fat graft promotes growth factors including vascular endothelial growth factor, platelet derived growth factor, transforming growth factor beta, and fibroblast growth factor which promote the process of the tissue repair.

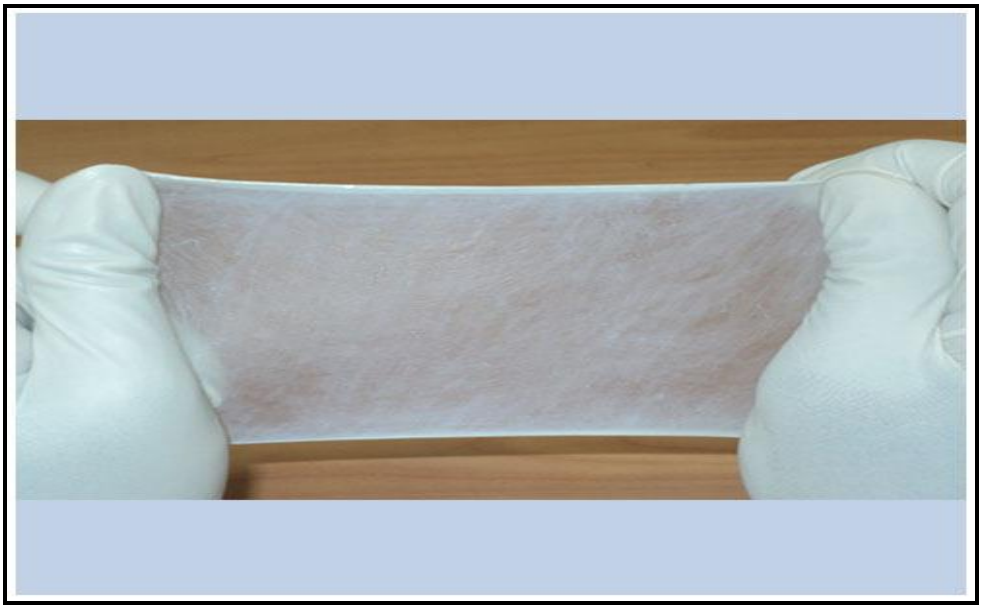
- “ Fat contains high population of **multipotent cells** referred to as adipose-derived stem cells which are similar in activity to those of the bone marrow derived mesenchymal stem cells which has the ability to differentiate into mesenchymal tissues such as endothelial and fibrous types promoting the healing process of the tympanic membrane”.

ADVANTAGES OF COLLAGEN AS GRAFT

- Collagen is one of the major components of extracellular matrix which has some important physical properties that aid in healing of TM perforations.
- It has **high tensile strength**
- **Flexibility** is an important property which helps in maintaining the physiology of tympanic membrane
- It also has other important properties like non-toxicity, non-reactivity and non-carcinogenicity.
- Tympanic membrane normally said to contain collagen type I,II,III,IV,VI in its lamina propria layer.
- Collagen helps in maintaining the intergrity and resilience of the tympanic membrane which is important in maintaining the physiological functions of normal TM.
- Since collagen is the constituent of the normal TM and it promotes the healing factors, collagen when used as the graft material promotes healing.
- Allows the patient's fibroblasts to grow and proliferate on the graft.
- Attachment of the fibroblast cells was facilitated by the collagen
- It has good manipulation properties,
- Collagen easily adheres to the TM surface

- Collagen grafts are fully transparent and hence the margins of the perforations can be easily seen by the surgeons.

- It also facilitates monitoring of the post procedure events due to its transparency



DISADVANTAGE

- Immunological reaction to bovine collagen.

HISTORY

The tympanic membrane perforation closure for hearing improvement was confined to prosthetic usage in the past.

- The prosthesis made of pig's bladder membrane stretched on ivory tube was first used by ***Banzer*** in 1640.

- Simple ball of moist cotton was used agaist the perforation by ***Yearsley*** in 1841. This method is still used today occasionally.

- ***Toynbee*** in 1853 devised a prosthesis made of thin rubber disc with thin silver wire stem to assist in its placement. He termed it as "ARTIFICIAL MEMBRANA TYMPANI".

- The still widely used paper patch method was introduced by ***Blake*** in 1887.

- Various other prosthesis made of different sheets, membranes or tubes which is closed at one end and opened at the other to occlude the tympanic membrane perforation or as a substitution for the tympanic membrane when it is absent was used over years

- ***"Korogel Insert"*** devised by ***Pohlman*** consists of a tube closed at one end and made of plastic material in different shapes and sizes to fit the individual ear was the most successful and useful prosthesis introduced.

- ***Roosa*** in 1876 used cautery by Silver nitrate bead as the method of destruction of the perforation rim to promote healing and its closure.

- ***Okuneff*** in 1895 introduced Trichloroacetic acid as the cauterizing agent whish is still being used now.

- ***Joynt*** in 1919 found that cauterization of TM perforation rim followed by placing patch on it gave higher success rates.

- ***Linn*** found that application of moist cotton over the cauterized edges and repeated cautery at weekly intervals to be very effective.

- This method with few changes was used by ***Derlacki and Wright.***

- ***Berthold*** in 1878 described Myringoplasty as the surgical procedure for closure of permanent TM perforations. He used the court plaster against the perforation for three days to remove the epithelium and then used a thick skin graft.

- In 1952, ***Wullstein*** described a method of using split-thickness skin graft to close perforation.

- In 1953 ***Zollner*** shared his experience with similar graft. House then described the usage of full thickness skin graft from behind the ear. But the disadvantages of these type of grafts like excessive desquamation into the meatus requiring frequent cleaning and re-perforation of healed perforations because of ingrowth of stratified squamous epithelium from the sweat, hair follicles and sebaceous glands of the graft placed became evident.

- ***Zollner*** in 1952 used the fascia lata as the graft following the suggestion of ***Unterberger.***

- Temporalis fascia graft was used by ***Heermann*** in 1958.

- Vein graft usage was individually explained by ***Shea*** and ***Tabb*** in 1960. Usage of these connective tissue grafts lead to higher success rates.

- Meanwhile usage of bony meatal skin was used as the pedicle graft due to absence of glands and hair follicles and as it is elevated along with its periosteum it devoids the cutting across of one of these epithelial lined tubules, meatal skin is accustomed to the moisture retaining confines of the ear canal, rate of desquamation is less and it has self-cleansing property by outward migration of the cornified layer.

- Adipose tissue was used as a graft material for the first time by ***Ringenberg*** in 1962.

- The most successful graft material used was Temporalis fascia graft with high success rates of 94-96%

- Down the century many auto and allografts like fascia, vein grafts, fat, skin, perichondrium, cartilage and Alloderm have been tried with varying success rates.

- Each grafts have their own advantages and disadvantages.

- Many xenografts and synthetic graft materials like paper patch, gelfoam plug and grafts of hyaluronic acid derivatives have been studied.

- Commercially available xenografts like porcine small intestine submucosa have also been tried.

- Recently many studies have been done using biomaterials such as silk fibroin, calcium alginate and chitosan.

- Collagen which is the component of TM and are found in extracellular matrix have also been tried.

- Unfortunately only limited studies have been carried out using collagen as the graft material.

- Collagen scaffolds have been used as the graft material in rats and have proven to be effective.

- Collagen-immobilized patch have been analysed and it showed 70% success rate which was comparatively equivalent to other biomaterials.

AIMS AND OBJECTIVES

1) To compare the effectiveness of collagen patch and fat plug for management of small tympanic membrane perforations as an OFFICE PROCEDURE.

2) To evaluate the patient benefits compared to surgical procedures & cost effectiveness

3) To evaluate improvement in audiometric pattern of hearing pre and post procedure.

4) To evaluate and compare the rate of healing in collagen patch and fat plug myringoplasty.

MATERIALS AND METHODS

STUDY PLACE

Rajiv Gandhi Government General Hospital, Chennai – 600003.

COLLABORATING DEPARTMENT

Upgraded Institute of Otorhinolaryngology

STUDY DESIGN

Prospective study

STUDY PERIOD

September 2013 toSeptember2015

INCLUSION CRITERIA

Age criteria – 15 – 50 years

1) 6 months following the previous ear surgery

2) Perforation in the pars tensa involving only one quadrant.

3) Absence of atrophic areas or calcific plaques adjacent to the perforation.

4) Normal tympanic cavity mucosa

5) Absence of any acute inflammation.

6) Absolute dryness for 3 months

7) Ossicular chain intergrity

8) Eustachian tube patent.

EXCLUSION CRITERIA

1) Septic foci of infections in nose & tonsils.

2) Marginal perforations

3) Perforations involving more than 1 quadrant

4) Active stage of infections

5) Tympanosclerotic patch.

6) Cholesteatoma foci.

PRE OP WORK UP

- History taking
- Clinical examination
- Examination on table
- Pure tone audiometry – pre & post procedure
- Routine blood investigations
- Follow up-2 months

DATA COLLECTION

Clinical

PATIENT SELECTION

- This prospective study comparing the effectiveness of closure of small tympanic membrane perforations using collagen patch and fat plug

myringoplasty was performed on 60 patients of which 22 were males and remaining 38 were females.

- Totally the patients with infectious cause for TM perforations were 29,traumatic cause were 21 and post myringoplasty were 10 of which 15 patients from the infectious cause 10 from traumatic cause and 5 from post myringoplasty was selected for collagen patch and 14 patients from the infectious cause ,11 from traumatic cause and 5 from post myringoplasty was selected for fat plug randomly.

- Patients were selected according to the above said inclusion and exclusion criteria.

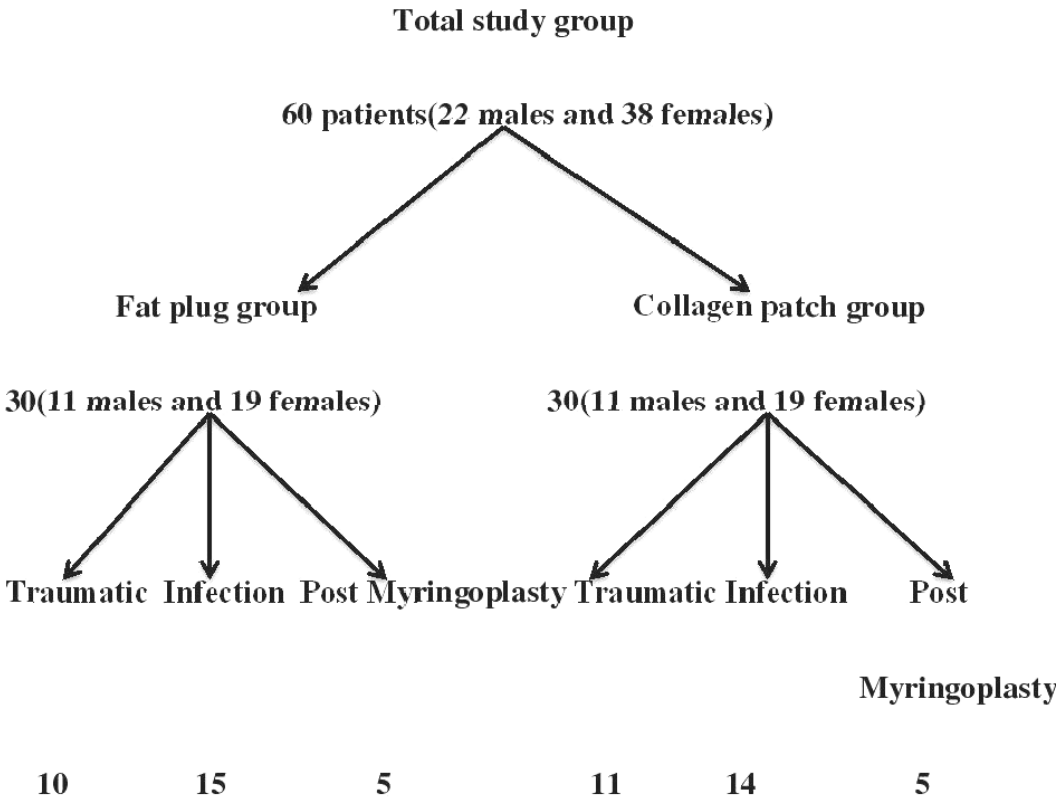
- A thorough history taking and clinical examination was proceeded in all patients and pre op work up was done.

- Pure tone audiometry was done and A-B gap was estimated at 0.5,1 and 2 kHz for all the patients for our comparative purpose.

- Procedure, advantages, disadvantages, other options were explained in detail to all the patients.

- Informed consent was obtained from all the patients after explaining that this procedure may be followed by a traditional myringoplasty after watchful follow-up.

- The consent of the institutional review board was obtained.



TECHNIQUE

This procedure in all the patients were carried out as office procedure under local anaesthesia by placing 4% xylocaine solution soaked cotton ball in the external auditory canal.

- ❖ Patients were placed in supine position with head placed under the head ring and head turned to opposite side.
- ❖ Under strict aseptic precautions, using Hopkins O degree endoscope, local anaesthesia given using 2% xylocaine mixed with 1 in 100000 adrenaline in the EAC.
- ❖ Using sharp dissector margins of the perforation was freshened.

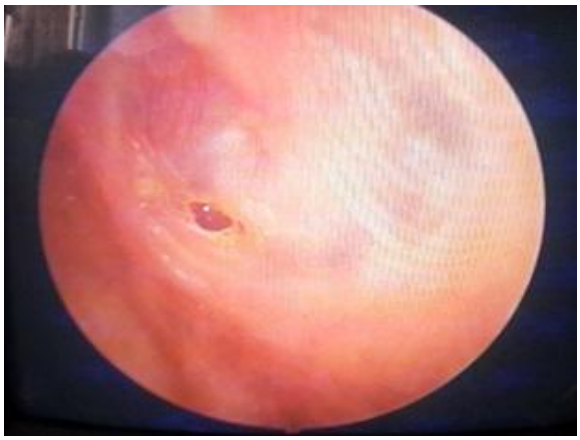
- The final estimation of the size of perforation was done after freshening the margins to estimate the amount of collagen patch or the fat graft to be used.

COLLAGEN PATCH TECHNIQUE

- Collagen sheet was trimmed approximately to the size of twice or lesser to that of the perforation size and put in sterile saline solution.

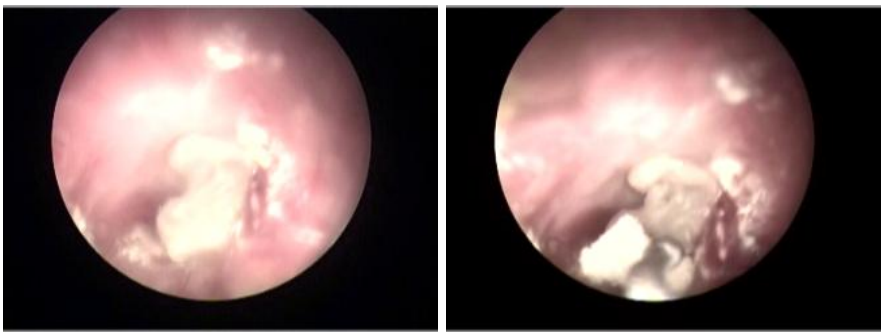
- Collagen patch was placed over the perforation .

- The collagen patch will stick to the underlying TM and to keep it in position to promote healing, pieces of gelfoam were kept on and around the collagen patch.

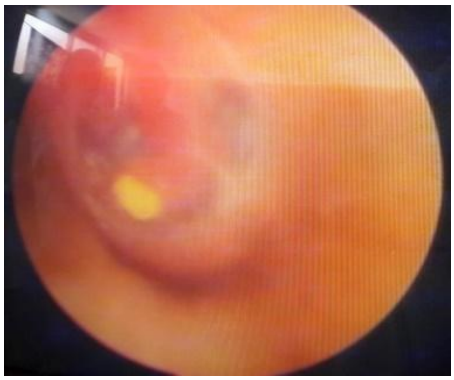


- Pre op TM perforation

- Freshening of perforation edges



- Collagen patch placement and gel foam placement



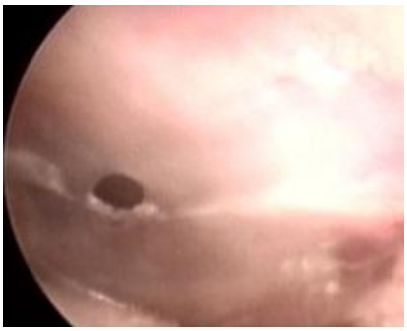
- Post op TM at 7 days

- Healed CP at 2 months

FAT PLUG MYRINGOPLASTY

- Ear lobe was infiltrated using 2% lignocaine solution and then a small incision was made on the medial aspect of ear lobule and skin undermined and fat of size twice as that of the perforation was harvested and put in saline solution.

- The incision was sutured using 3-0 ethylon.
- The fat graft was trimmed approximately to the size of twice or lesser to that of the perforation size and under endoscopic visualization fat graft was placed over the perforation and using a straight pick fat was plugged into the perforation like the hourglass.
- Oversized fat plug may cause a tear of the tympanic membrane or may lead to atrophy or necrosis by stetching of the tympanic membrane.
- Dehiscence of the graft should be avoided by plugging of undersized graft.
- The graft was humidified by placing pieces of gelfoam on and around the graft.

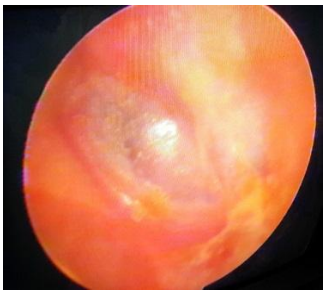


- Pre op perforation

Image showing freshening of perforation edges

- Plugging in of fat graft

- Gel foam placement



- Post op healed CP at 2 months

- After placing collagen patch or fat plug and fixing it in place with gel foam,Antibiotic eardrops soaked gelfoam pieces were kept in the EAC.

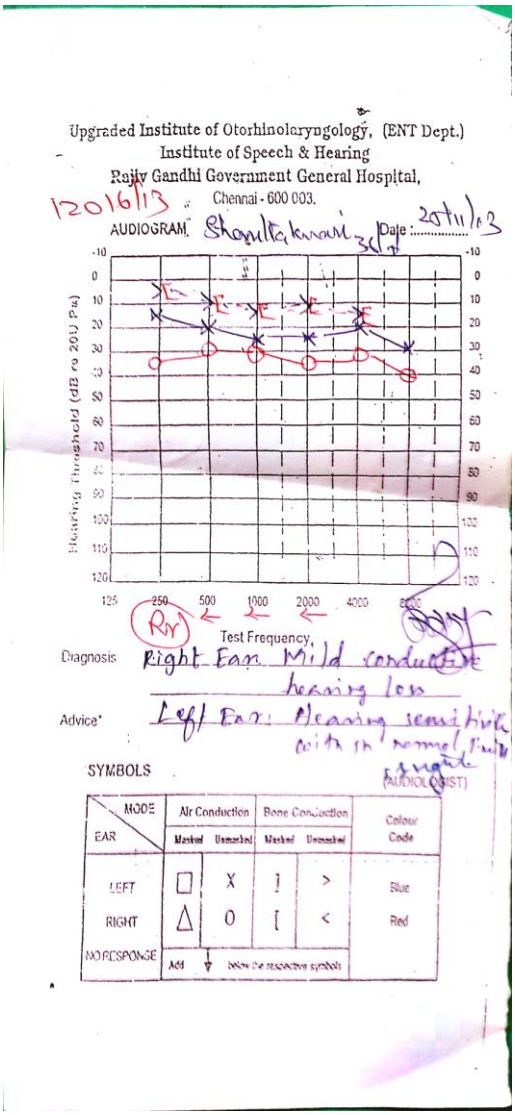
- Medicated ear wick was placed.

- No ear dressing was used.

- After observation for about half an hour patient was sent home with antibiotics, analgesics and nasal decongestant drops for 1 week.
- All patients were adviced to keep the ear dry, avoid headbath, avoid straining, nose blowing for atleast 1 month.
- Patients were instructed to regularly follow up in the OPD at the end of 7,14,30 and 60 days.
- Ear wick was removed at the end of one week.
- The appearance of dimeric tympanic membrane was monitored in each follow up.
- Audiometry was done at the end of 1 and 2 months.
- The failure was determined by the absence of appearance of dimeric tympanic membrane at the end of 1 month and complete closure of tympanic membrane at the end of two months.

RESULT

The outcome measures of this study was based on perforation closure, post operative A-B gap, absence of any complications like infection, persisting defect in the tympanic membrane, collagen patch extrusion or otomycosis or small sized fat graft.



Upgraded Institute of Otorhinolaryngology, (ENT Dept.)
Institute of Speech & Hearing
Rajiv Gandhi Government General Hospital,
Chennai - 600 003.

12/6/13

AUDIOGRAM Shanthakumari 30 Date : 20/11/13

Hearing threshold (dB re 20U Pa)

Test Frequency,

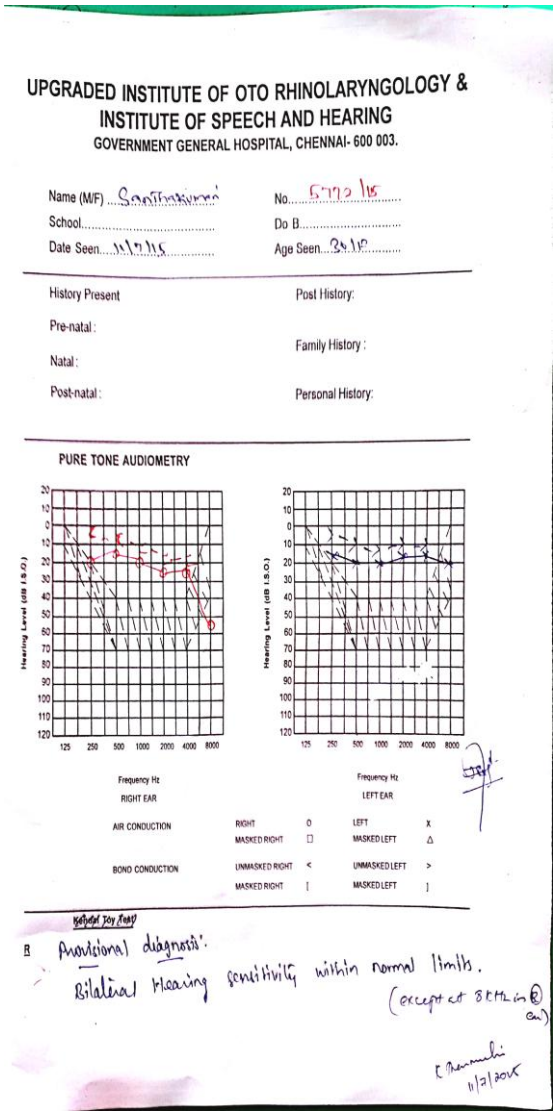
Diagnosis Right Ear Mild conductive hearing loss

Advice Left Ear: Hearing sensitivity with in normal limits

SYMBOLS

MODE / EAR	Air Conduction Masked	Air Conduction Unmasked	Bone Conduction Masked	Bone Conduction Unmasked	Colour Code
LEFT	□	X	]	>	Blue
RIGHT	△	O	[	<	Red
NO RESPONSE	Add ▽ below the respective symbols				

(AUDIOLOGIST)



UPGRADED INSTITUTE OF OTO RHINOLARYNGOLOGY & INSTITUTE OF SPEECH AND HEARING
GOVERNMENT GENERAL HOSPITAL, CHENNAI- 600 003.

Name (M/F) Santhakumari No. 5772/15
School Do B
Date Seen 11/7/15 Age Seen 34 Y/F

History Present
Pre-natal :
Natal :
Post-natal :
Post History :
Family History :
Personal History :

PURE TONE AUDIOMETRY

Hearing Level (dB I.S.O.)

Frequency Hz
RIGHT EAR

Frequency Hz
LEFT EAR

AIR CONDUCTION RIGHT O LEFT X
MASKED RIGHT □ MASKED LEFT △
BONE CONDUCTION UNMASKED RIGHT < UNMASKED LEFT >
MASKED RIGHT [MASKED LEFT]

R Provisional diagnosis:
Bilateral Hearing sensitivity within normal limits.
(except at 8KHz in R ear)

11/7/2015

STASTICAL ANALYSIS AND RESULTS

The study involved 60 patients totally and they were allotted into two groups of 30 in each group. The patients in the first group underwent collagen patch technique and the patients in second group underwent fat plug myringoplasty.

The study included age group of patients between 15-50 years.

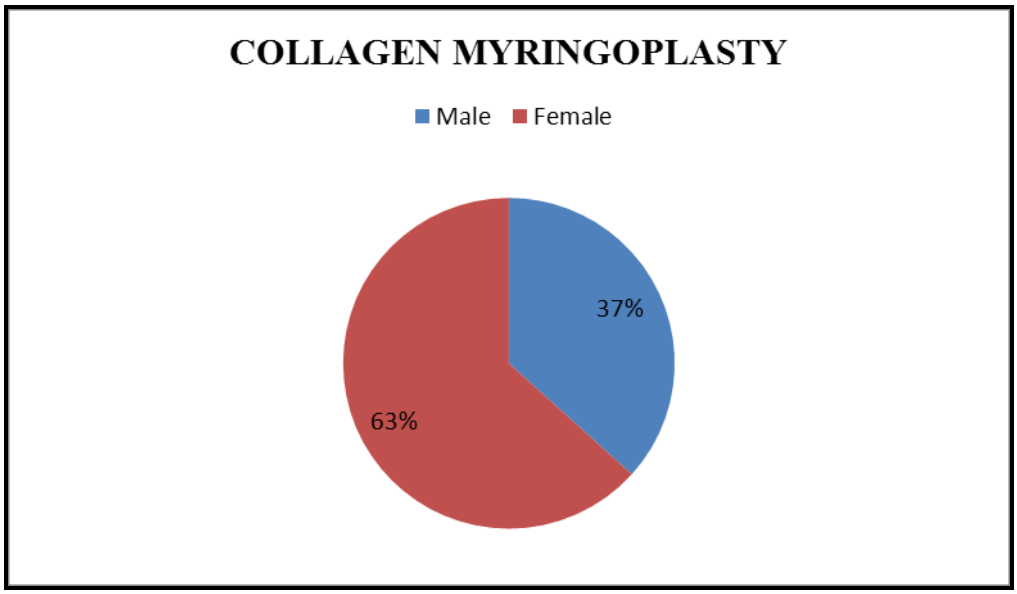
Age	Collagen patch technique	Fat plug myringoplasty
Mean	33.63	36.03
Standard deviation	9.481	7.09

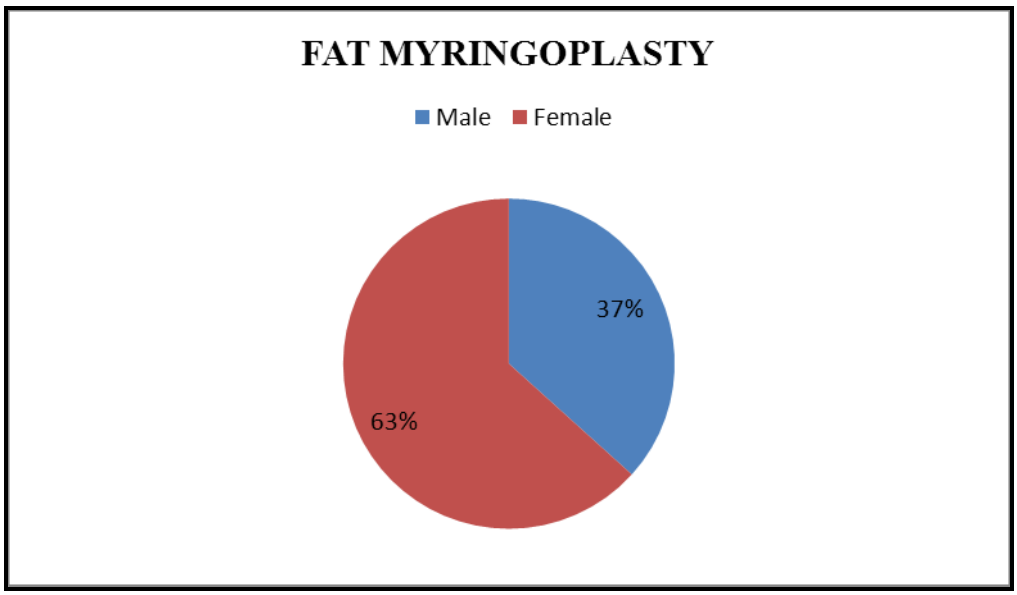
Variable	Collagen myringo plasty	Fat myringo plasty	Test done	Test value	P value
Age(mean,SD)	33.63,9.481	36.03,7.09	Independent Sample T	-1.112 dF-58	0.271

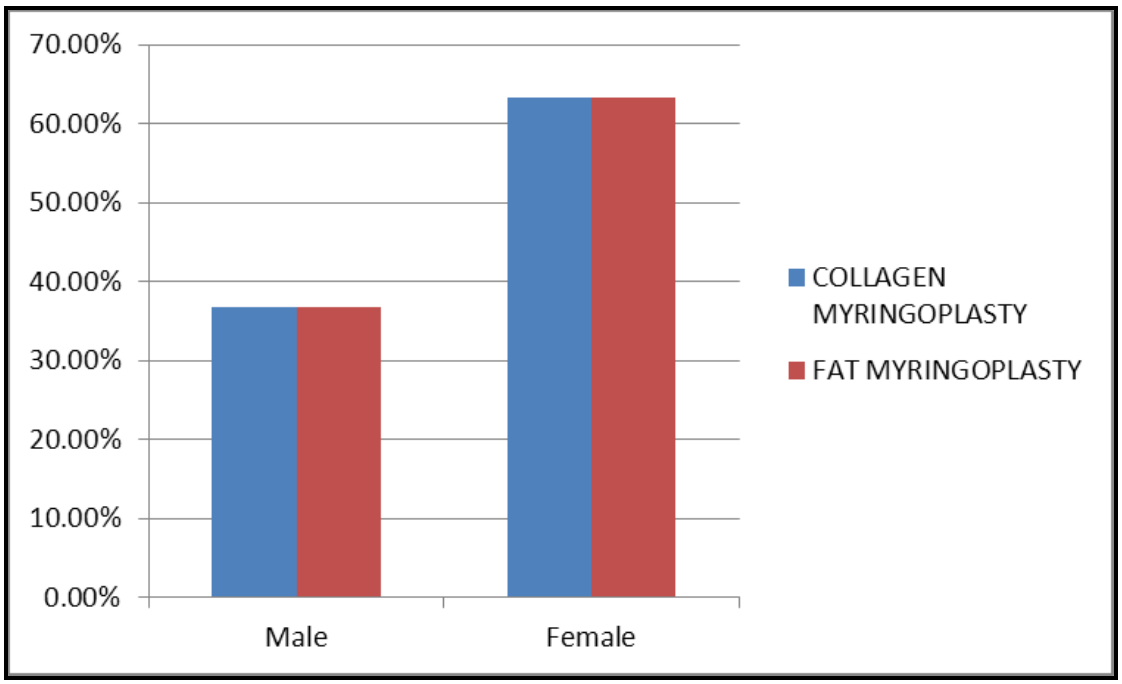
Mean age of patients in collagen group in our study was 33.63 years & mean age in fat group was 36.03 years.

Sex	Collagen Myringoplasty	Fat Myringoplasty
Male	11(36.7%)	11(36.7%)
Female	19(63.3%)	19(63.3%)

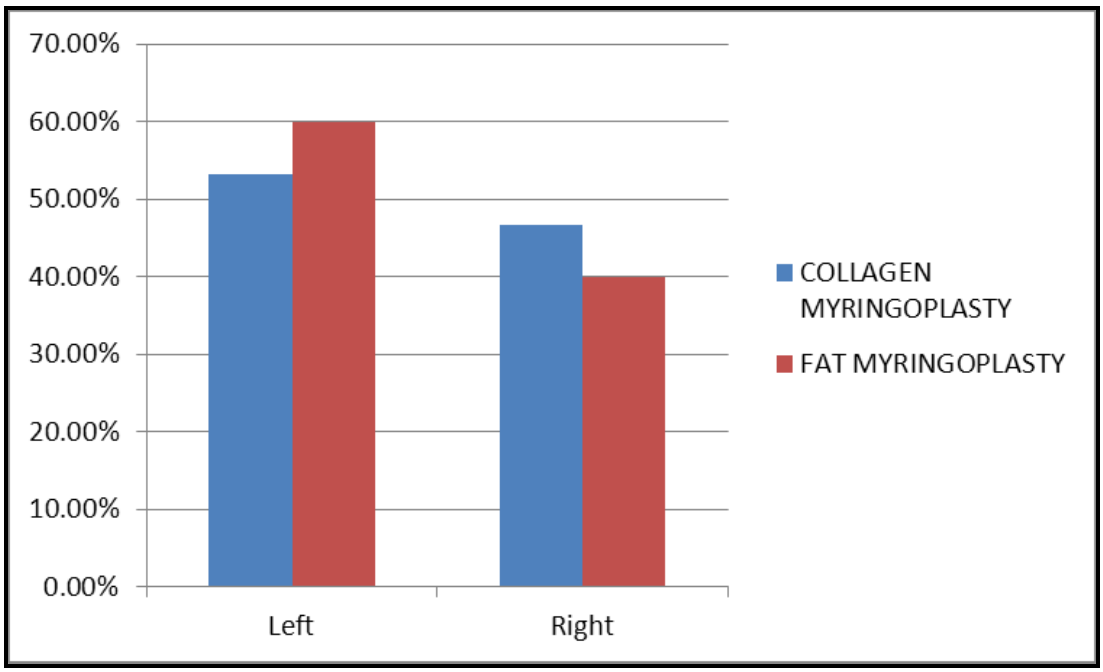
All pts in our study were equally divided in both groups with 11 male & 19 female in each group

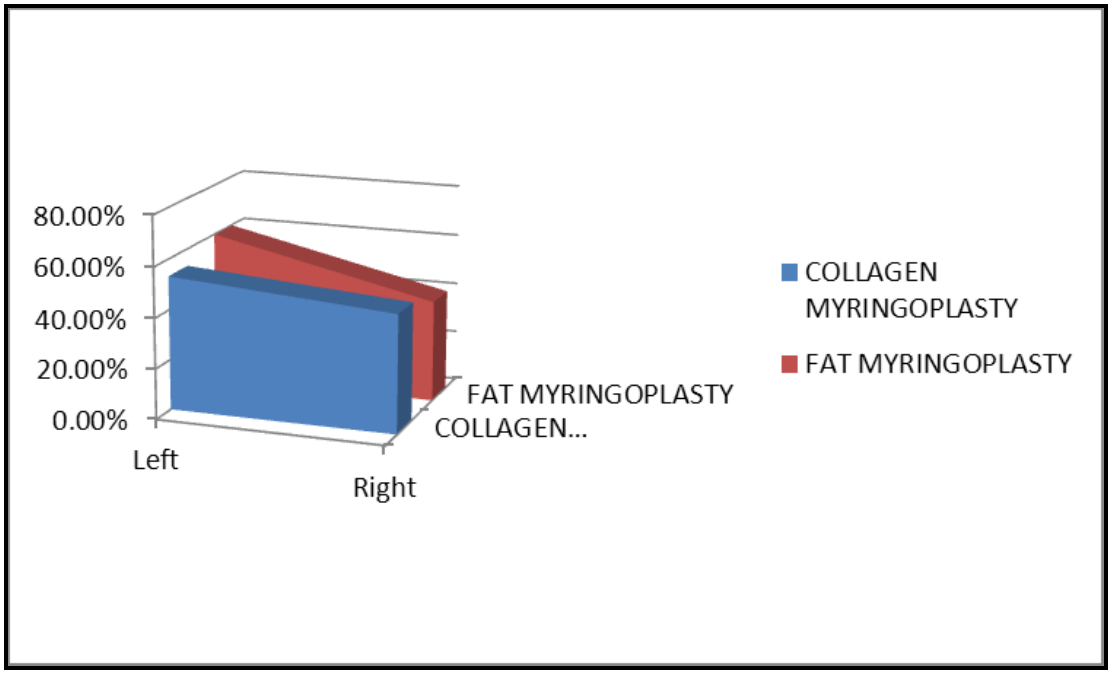






Side of perforation	Collagen myringoplasty	Fat myringoplasty
Left	16(53.3%)	18(60%)
Right	14(46.7%)	12(40%)





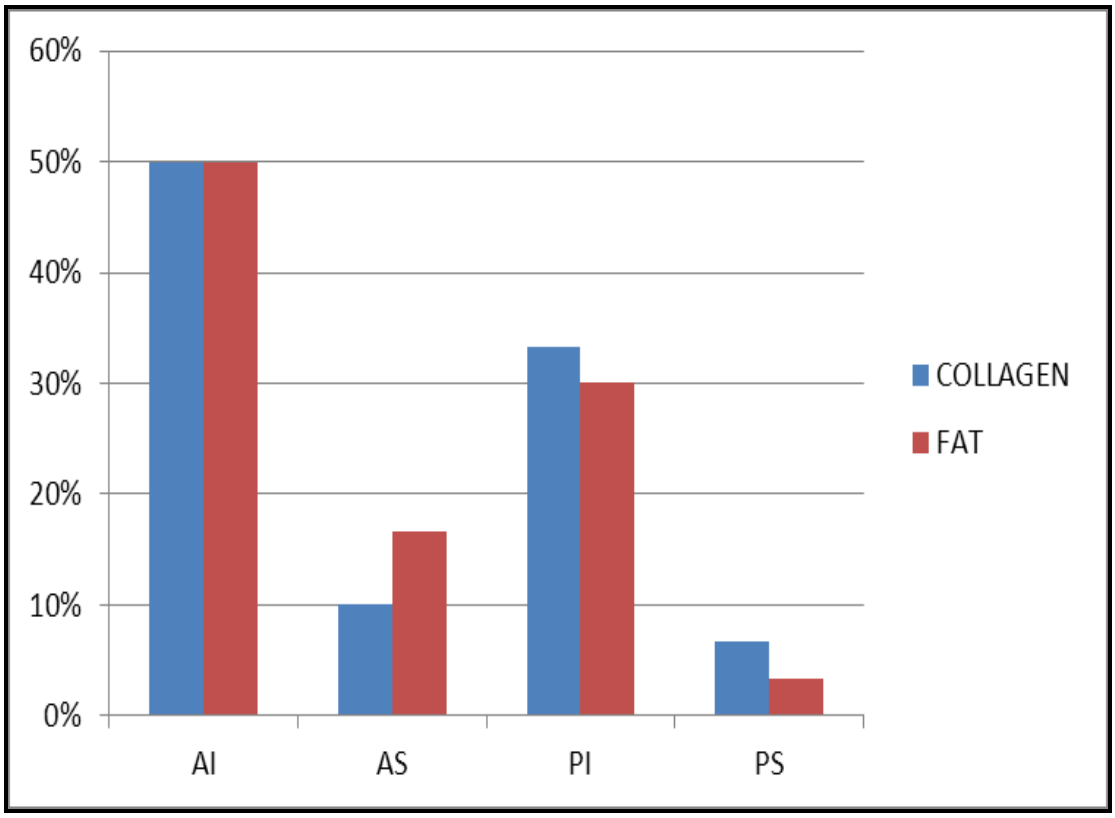
Side of perforation	Collagen myringoplasty	Fat myringoplasty
Left	16(53.3%)	18(60%)
Right	14(46.7%)	12(40%)

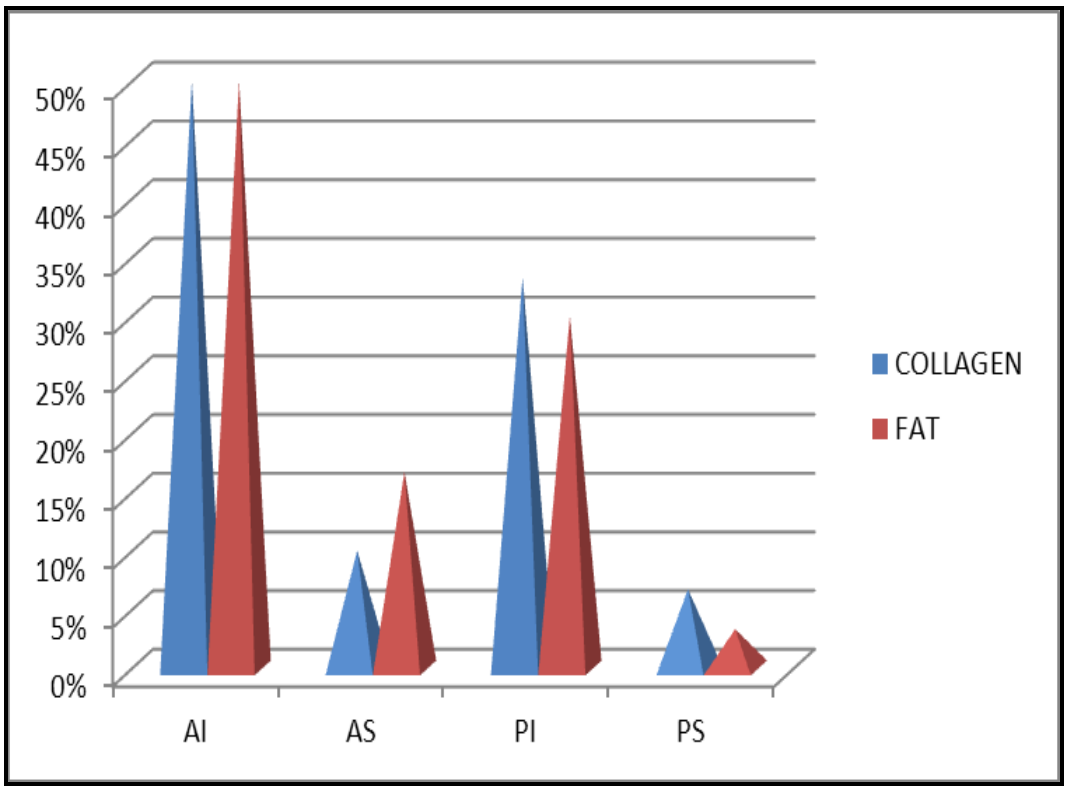
Test done –CHI SQUARE TEST

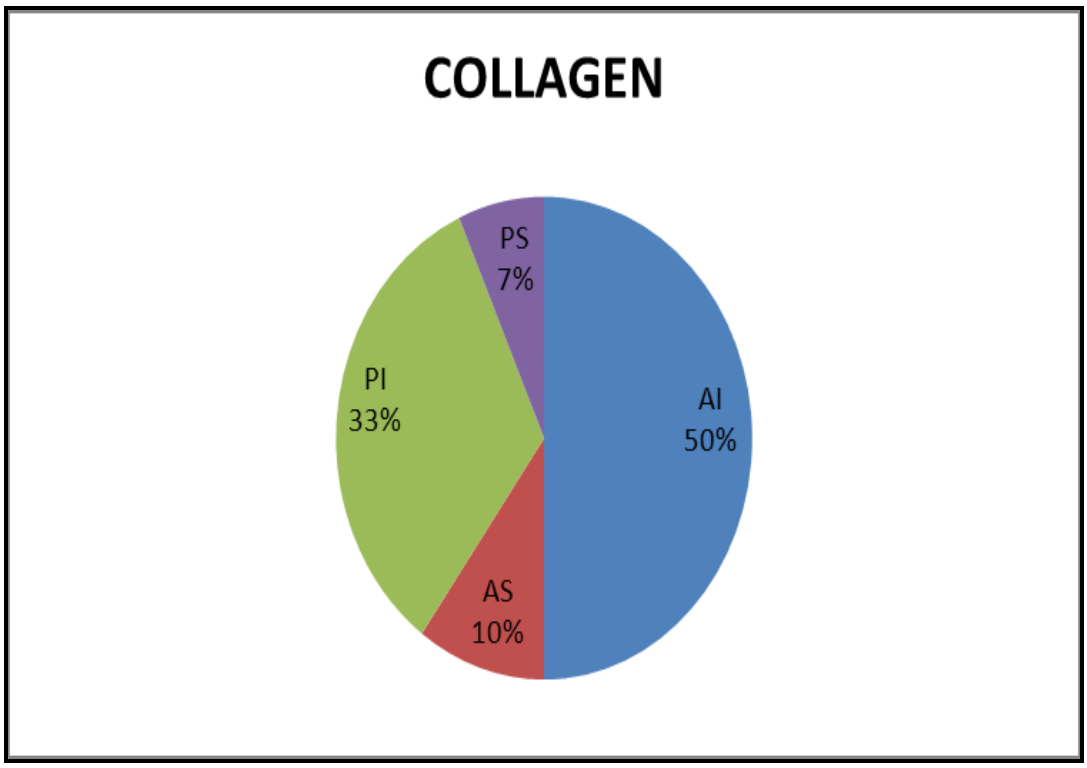
Test Value-0.271,dF-1

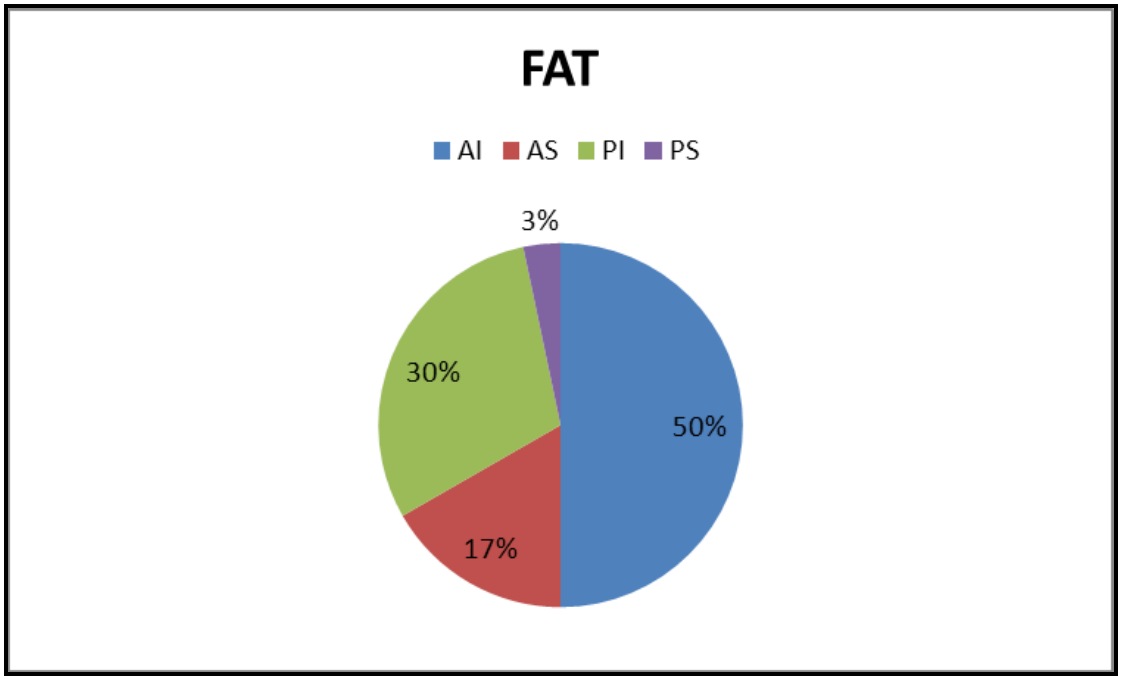
P value=0.602

Quadrant perforation	Collagen	Fat
AI	15(50%)	15(50%)
AS	3(10%)	5(16.7%)
PI	10(33.3%)	9(30%)
PS	2(6.7%)	1(3.3%)




50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
AI
AS
PI
PS
COLLAGEN
FAT


COLLAGEN
PS
7%
PI
33%
AI
50%
AS
10%



Quadrant perforation	Collagen	Fat
AI	15(50%)	15(50%)
AS	3(10%)	5(16.7%)
PI	10(33.3%)	9(30%)
PS	2(6.7%)	1(3.3%)

Test done-Fischer exact test

Test value=1.005

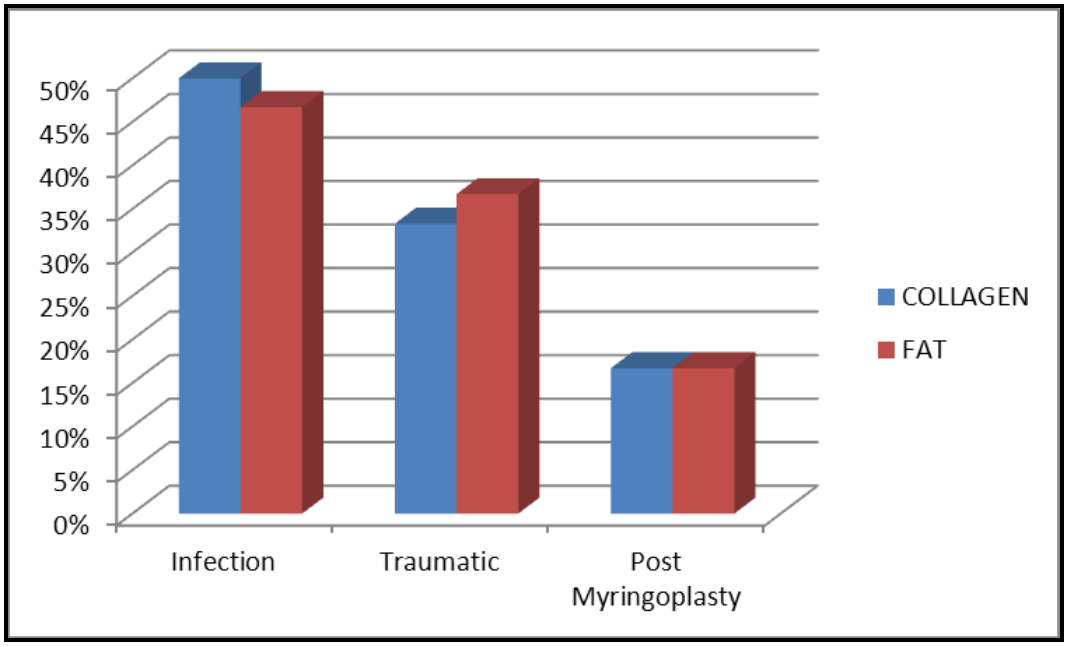
P value-0.829

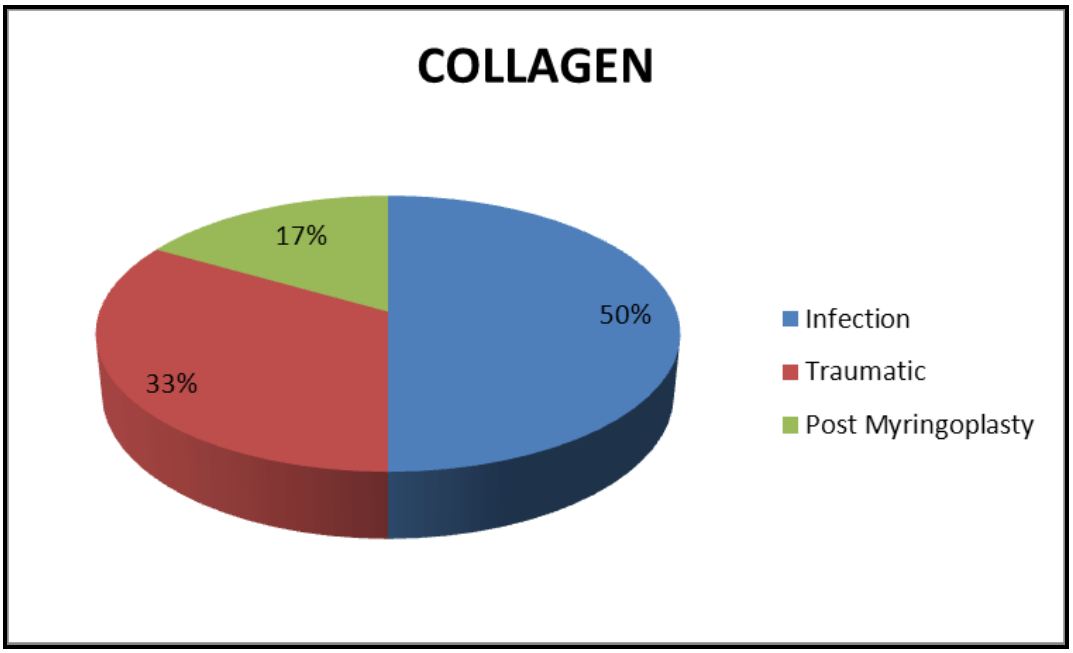
Based on our study , ANTERIOR quadrant perforations were found to be more in our study & the most common was ANTERO-INFERIOR quadrant.

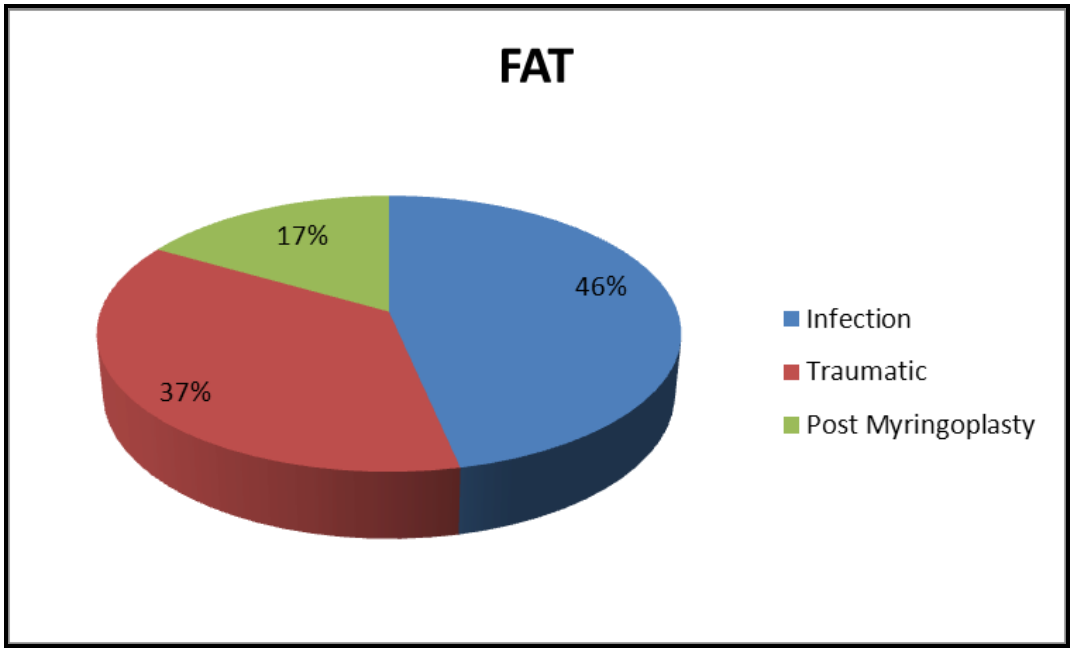
Superior quadrant perforations were comparatively less in our study.

CAUSES OF TM PERFORATIONS

Causes	Collagen	Fat
Infection	15(50%)	14(46.7%)
Traumatic	10(33.3%)	11(36.7%)
Post Myringoplasty	5(16.7%)	5(16.7%)







Causes	Collagen	Fat
Infection	15(50%)	14(46.7%)
Traumatic	10(33.3%)	11(36.7%)
Post Myringoplasty	5(16.7%)	5(16.7%)

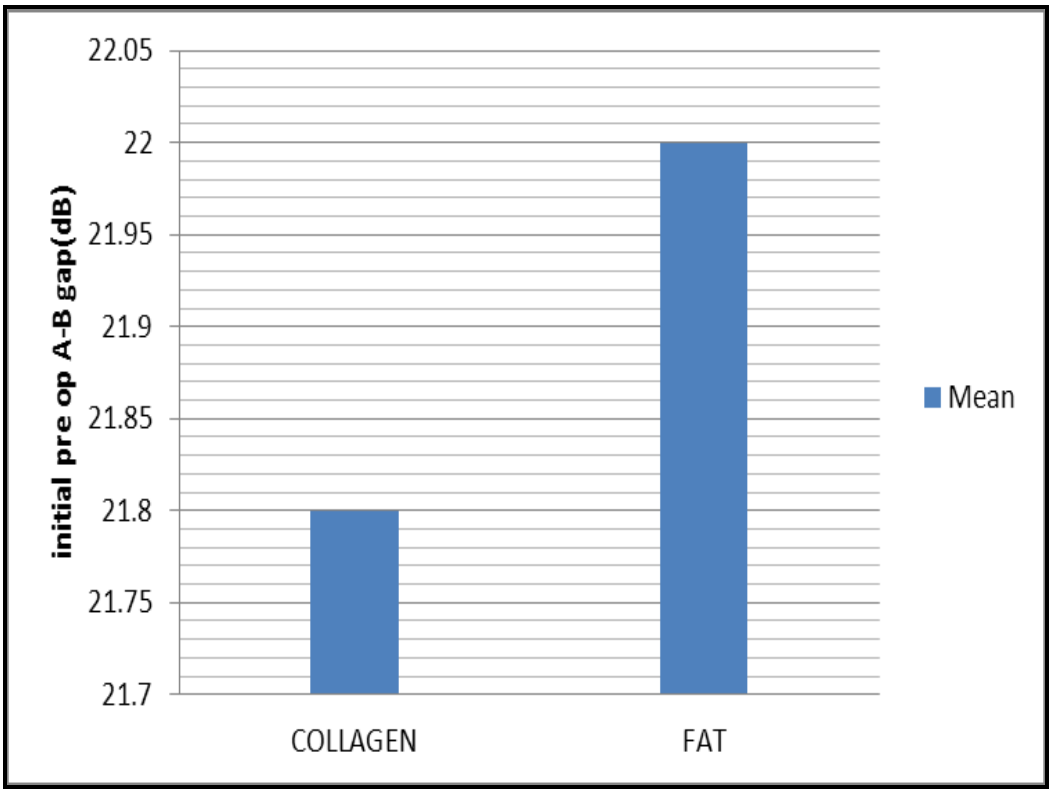
Test done-CHI SQUARE

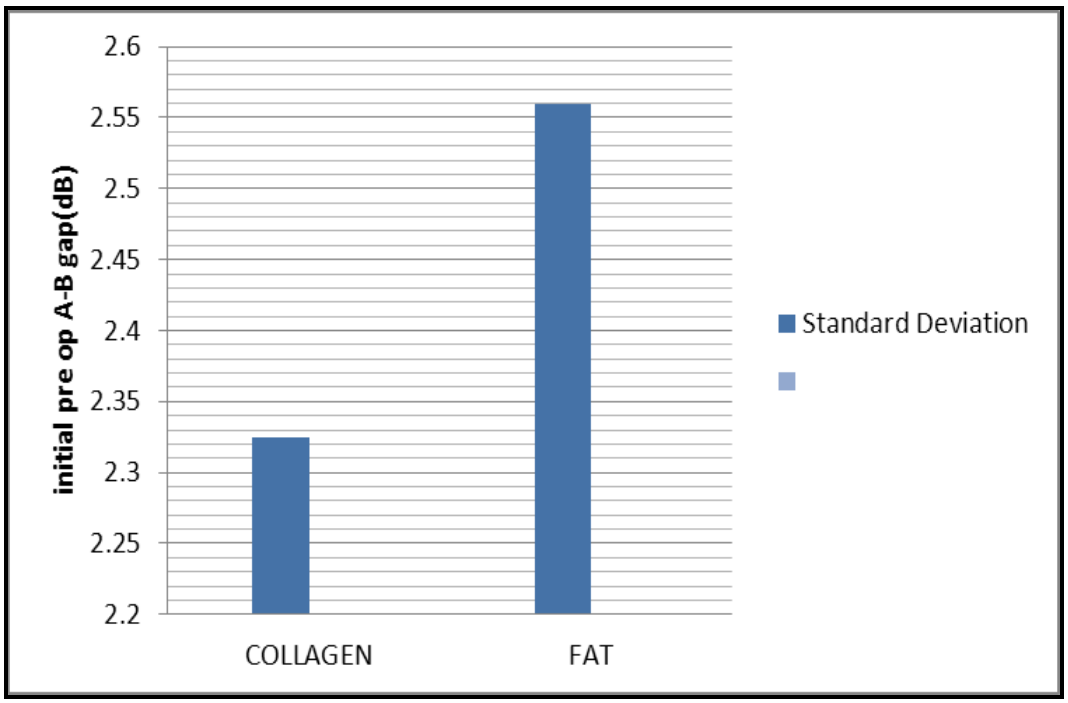
Test value-0.082 dF-2

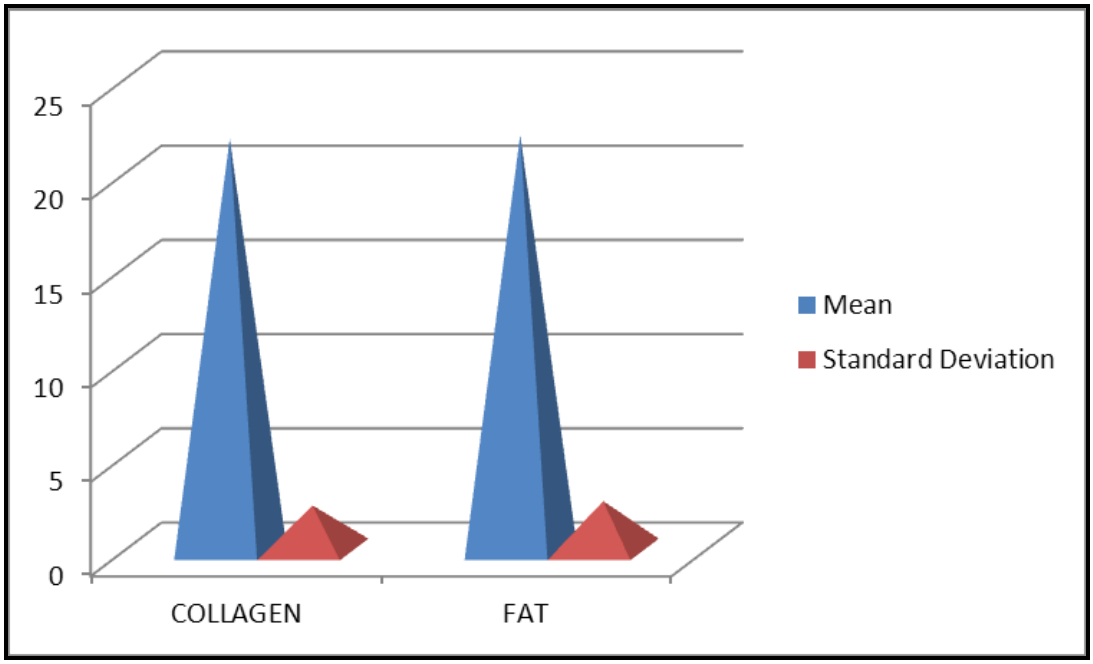
P value=0.960

In our study, Infective & Traumatic causes of perforation was found at a higher level. Post-myringoplasty cases were found to be rare.

PRE-OP AIR-BONE GAP EVALUATION IN PTA







INITIAL PRE OP A-B GAP(dB)	COLLAGEN	FAT
Mean	21.8	22
Standard Deviation	2.325	2.56

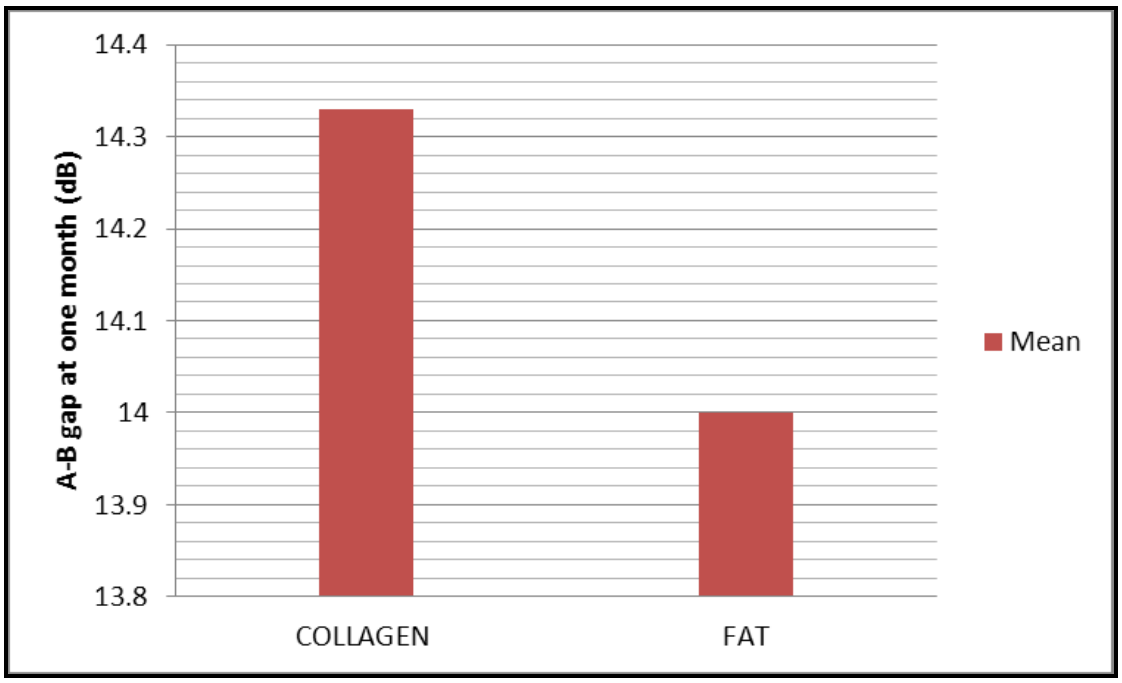
Test done-Independent Sample T test

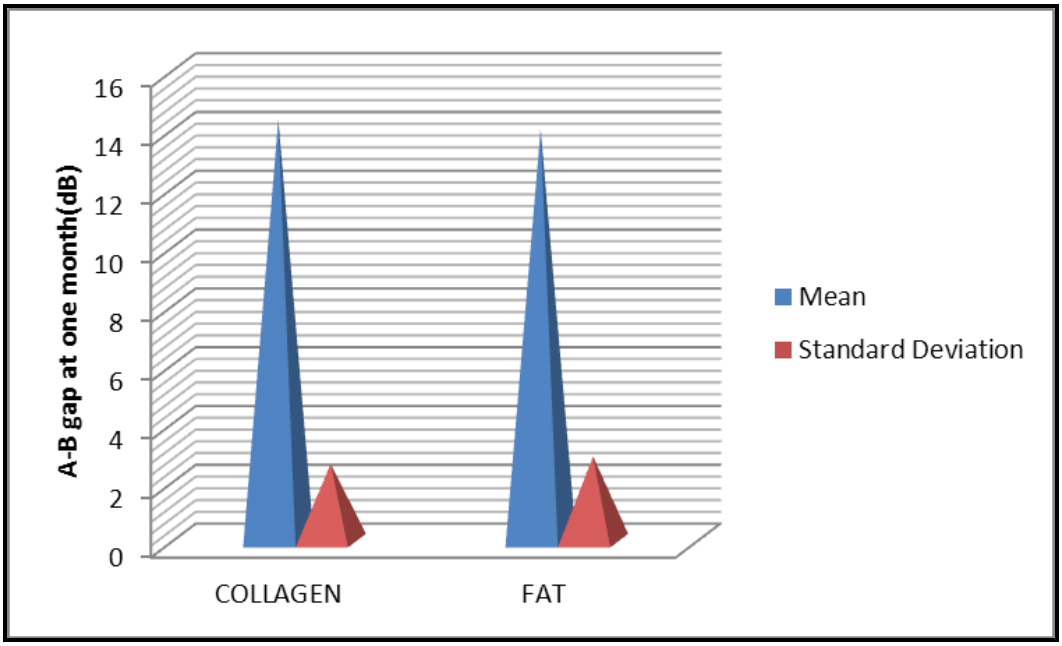
Test value-0.317 dF-58

P value=0.753

Initial pre-operative PTA done for our study group & mean A-B gap in collagen group was found to be 21.8 dB & mean A-B gap was found to be 22 Db .

POST OPERATIVE FOLLOW- UP : AIR- BONE GAP AT 1 MONTH FOLLOW-UP





A-B gap at one month (db)	Collagen	Fat
Mean	14.33	14
Standard Deviation	2.617	2.865

Test done-Independent Sample T test

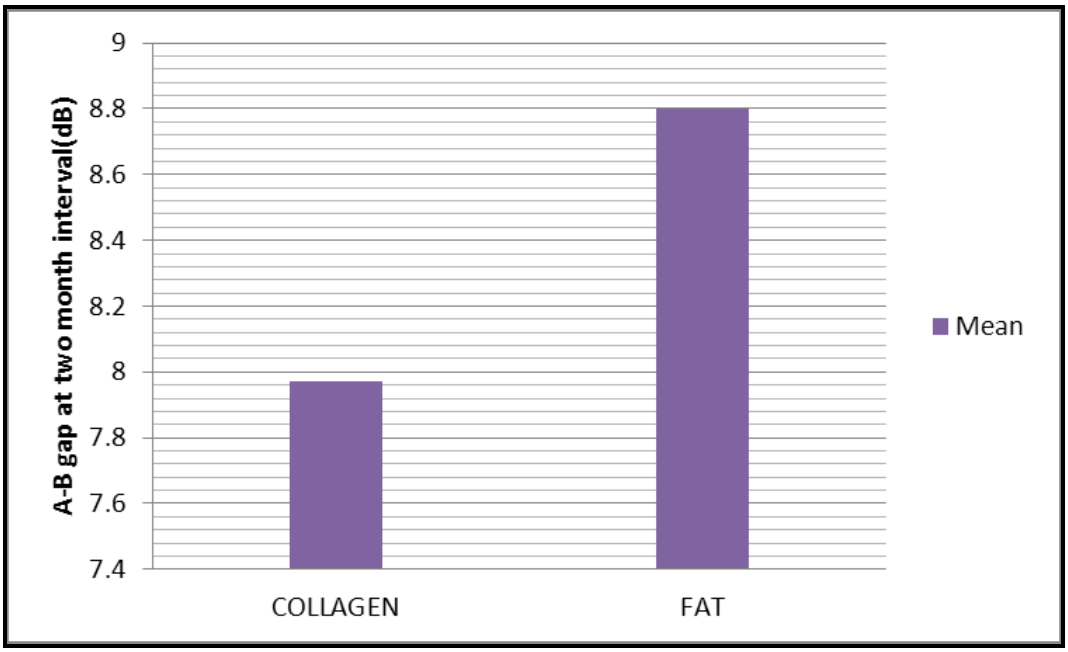
Test value-0.471 dF-58

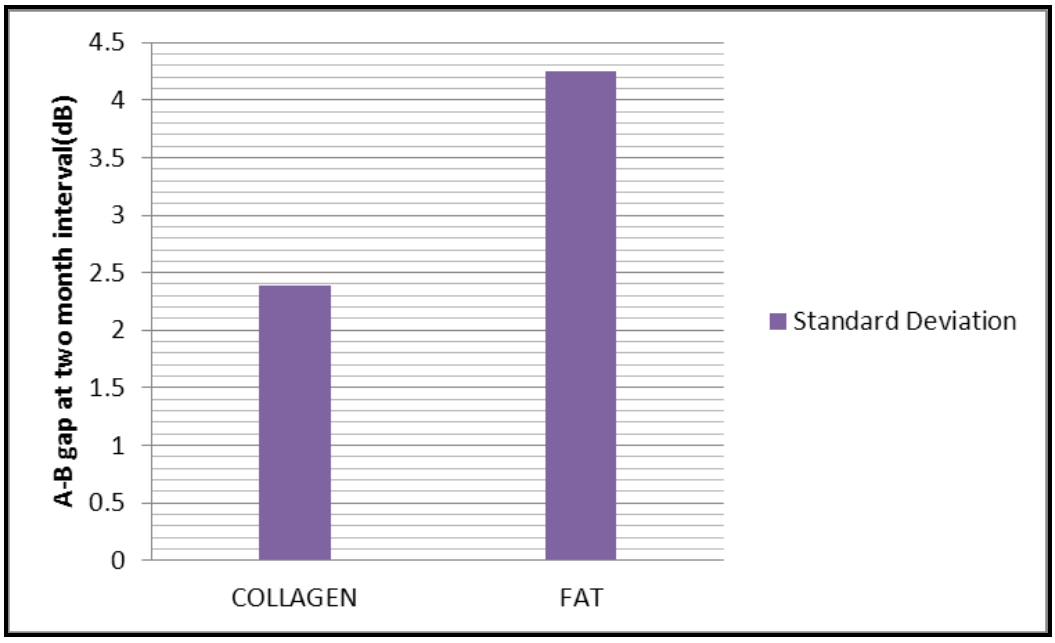
P value=0.640

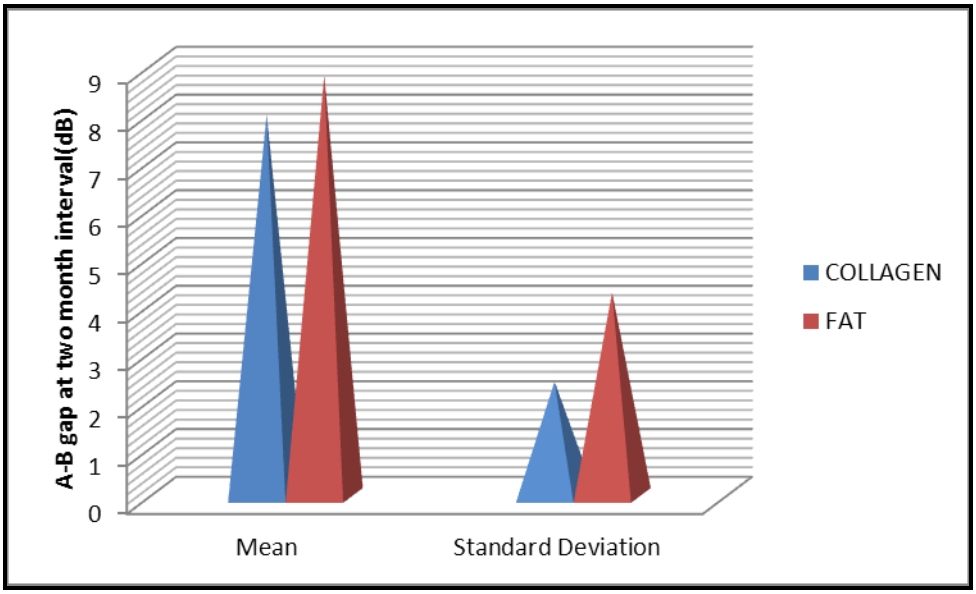
Patients were followed up at 1 month for PTA & AIR- BONE GAP calculated.

Mean A-B GAP at 1 month was 14.33 dB in collagen patients & 14 dB in fat plug group. So the amount of hearing improvement was found to be comparatively equal in both groups at 1st month follow up.

AIR-BONE GAP ESTIMATION AT 2ND MONTH FOLLOW UP







A-B gap at two months	Collagen	Fat
Mean	7.97	8.8
Standard Deviation	2.385	4.254

Test done-Independent Sample T test

Test value-0.936 dF-58

P value=0.354

Patients were followed up at 2nd month for PTA. Mean A-B GAP in hearing was found to be 7.97 dB in Collagen group & 8.8 dB in fat plug group. This shows a significant improvement in hearing in both groups & the amount of hearing improvement was almost the same.

COMPARISON OF AMOUNT OF HEARING IMPROVEMENT IN COLLAGEN PATCH & FAT PLUG GROUPS

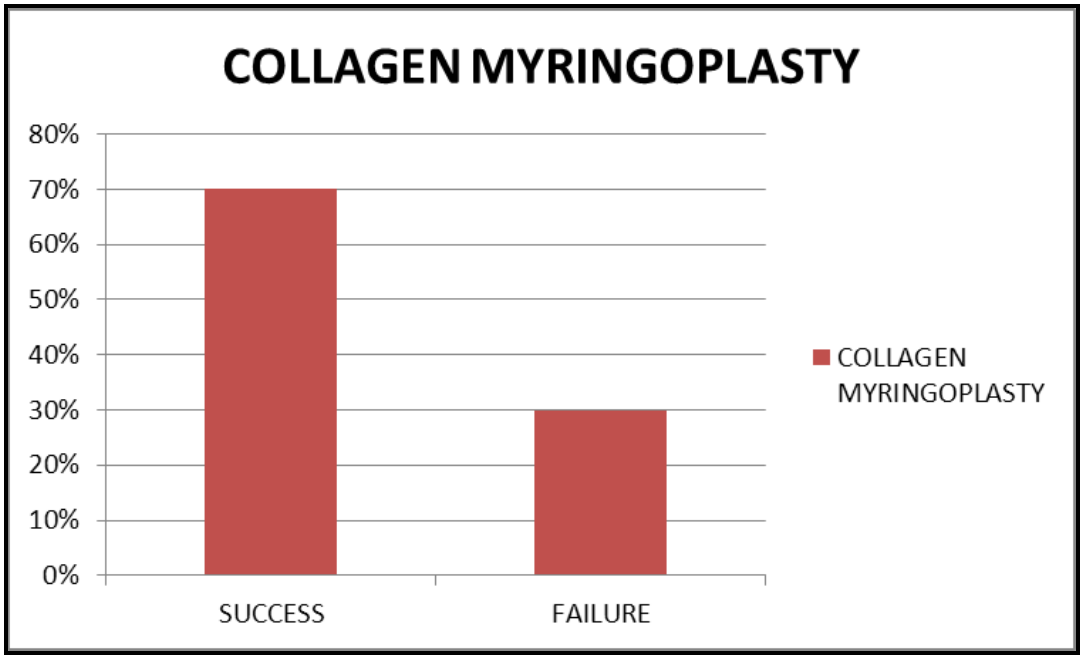
Procedure	Initial pre op a-b gap(db)	A-b gap at 1 month(db)	A-b gap at 2 months(db)	P value
Collagen	21.8(2.325)	14.33(2.617)	7.97(2.385)	<0.001
Fat	22(2.560)	14(2.865)	8.8(4.254)	<0.001

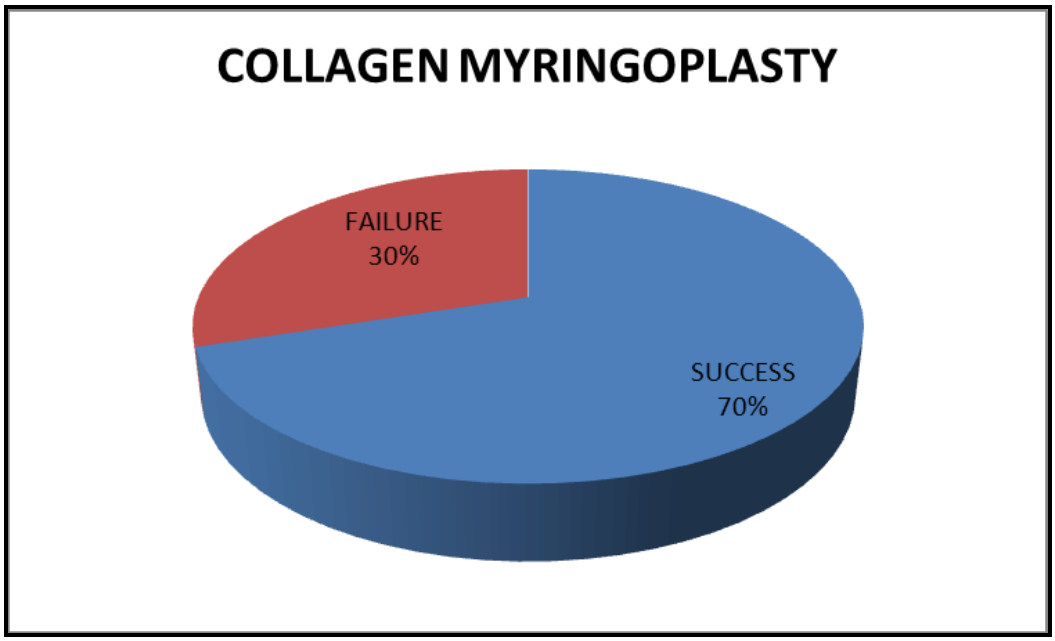
Test-Repeated measures ANOVA

The initial pre-op & post op A-B GAP at 1 & 2 months were compared in both groups using ANOVA test & P- VALUE was found to be significant in both the groups (P VALUE <0.001) . This shows that either collagen or fat can be used as a alternative in small tympanic membrane perforations for improvement in hearing.

SUCCESS & FAILURE RATES IN EACH GROUP

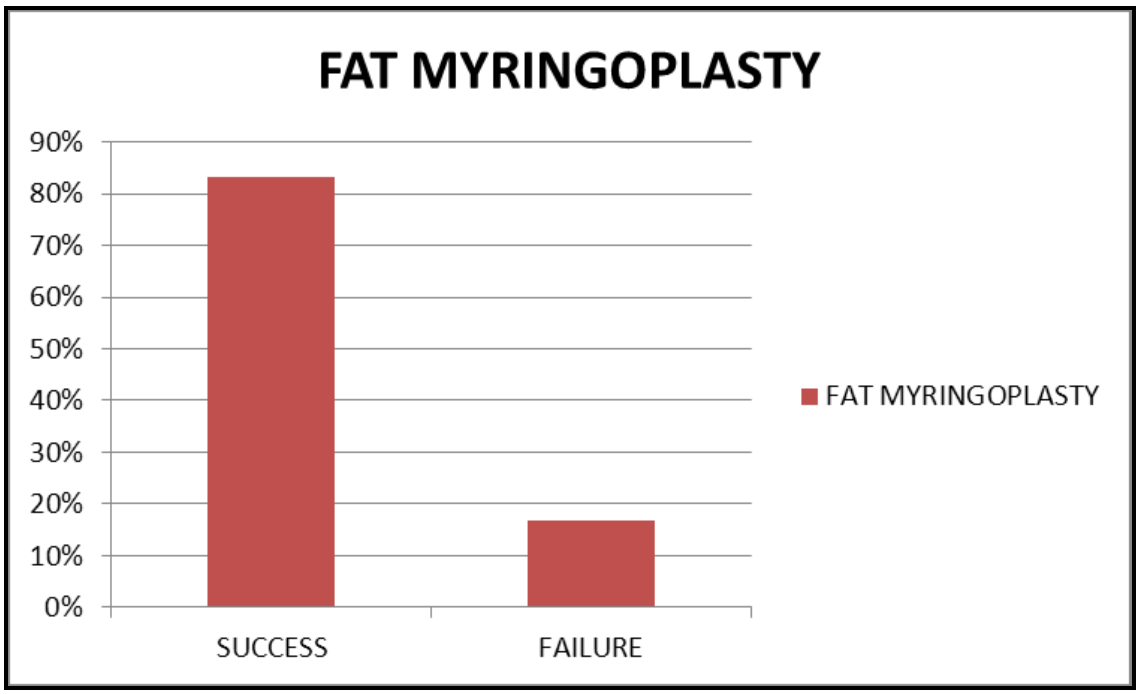
	Collagen myringoplasty
SUCCESS	21(70%)
FAILURE	9(30%)

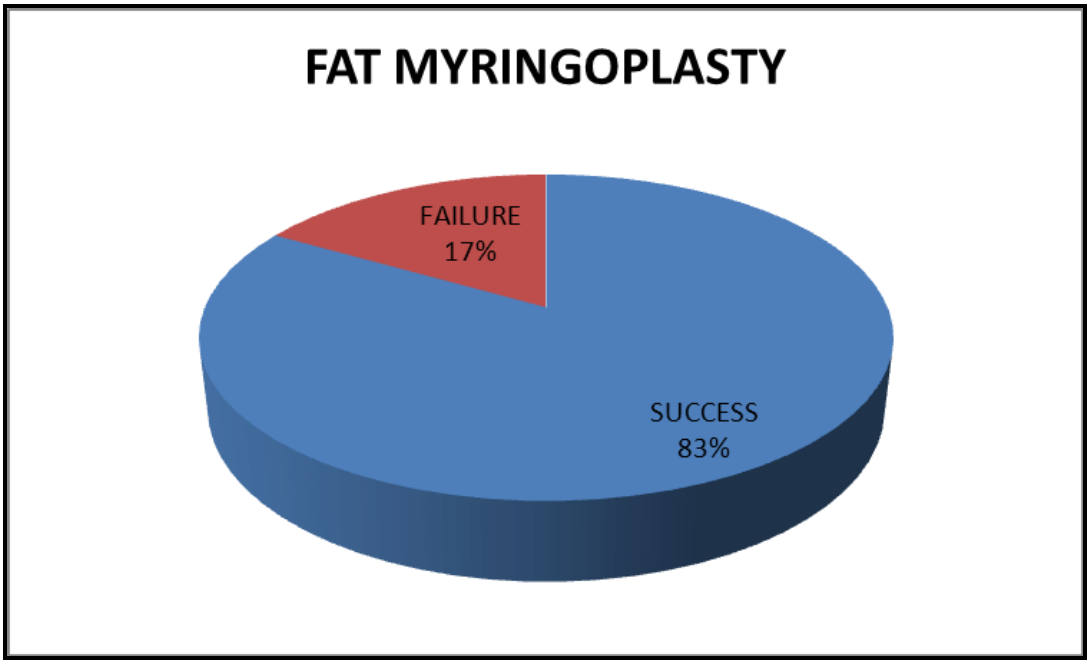

COLLAGEN MYRINGOPLASTY
80%
70%
60%
50%
40%
30%
20%
10%
0%
SUCCESS
FAILURE
COLLAGEN MYRINGOPLASTY


COLLAGEN MYRINGOPLASTY
FAILURE
30%
SUCCESS
70%

FAT PLUG

	Fat myringoplasty
SUCCESS	25(83.3%)
FAILURE	5(16.7%)





COMPARISON BETWEEN BOTH GROUPS

	Collagen myringoplasty	Fat myringoplasty
SUCCESS	21(70%)	25(83.3%)
FAILURE	9(30%)	5(16.7%)

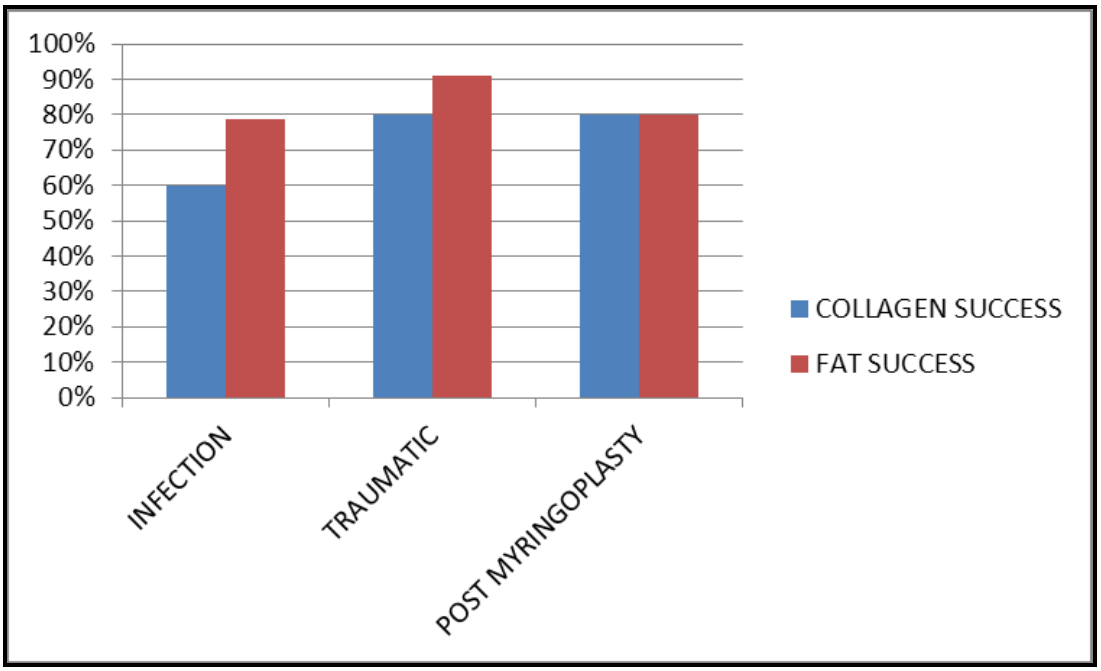
Test done-CHI SQUARE test

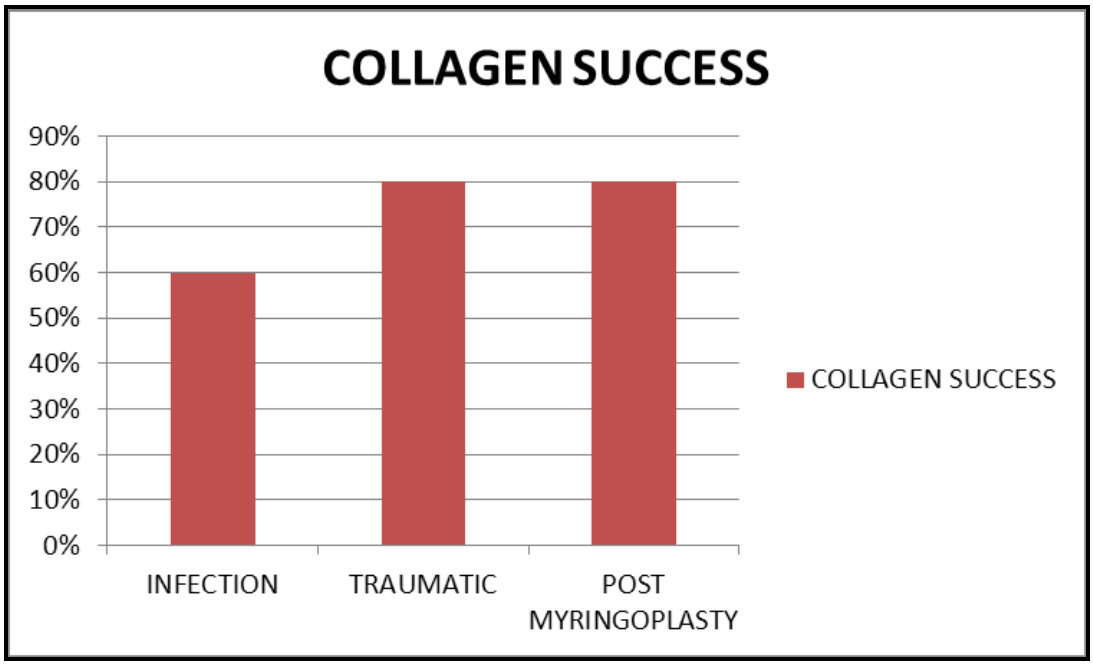
Test value-1.491

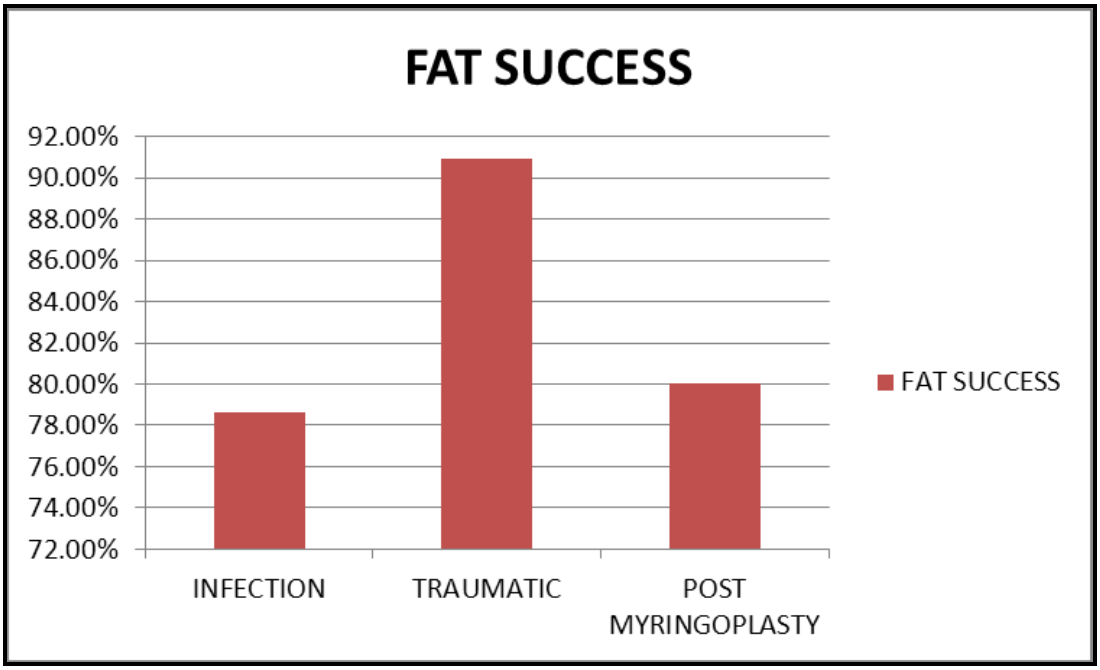
P value-0.222

In our study – COLLAGEN was found to be 70 % success & FAT plug was found to be 83.3% success. Comparison done using CHI-SQUARE test revealed a insignificant P value (P -0.222) . so collagen can also be used as a graft material with conventional fat plug for small perforations .

SUCCESS RATES DEPENDING ON CAUSES



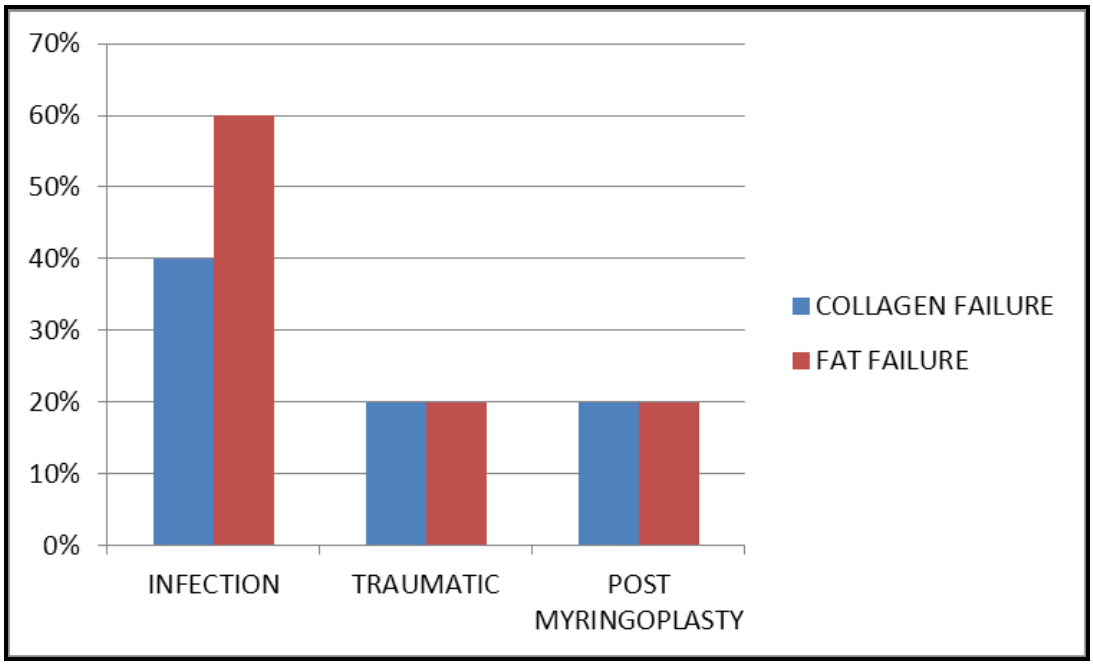


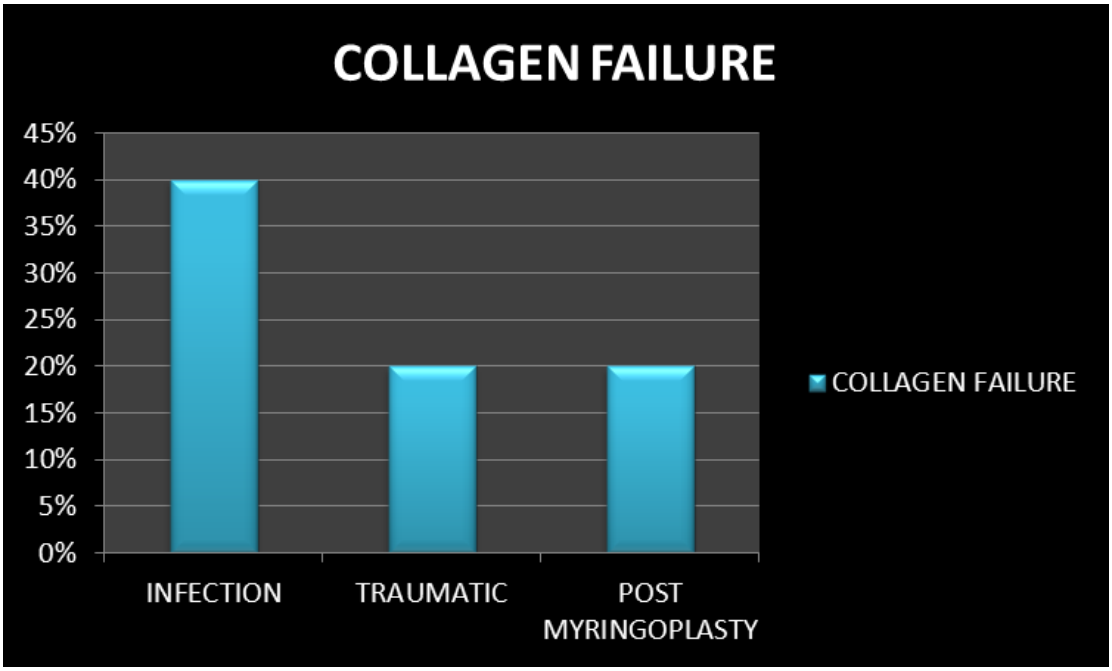


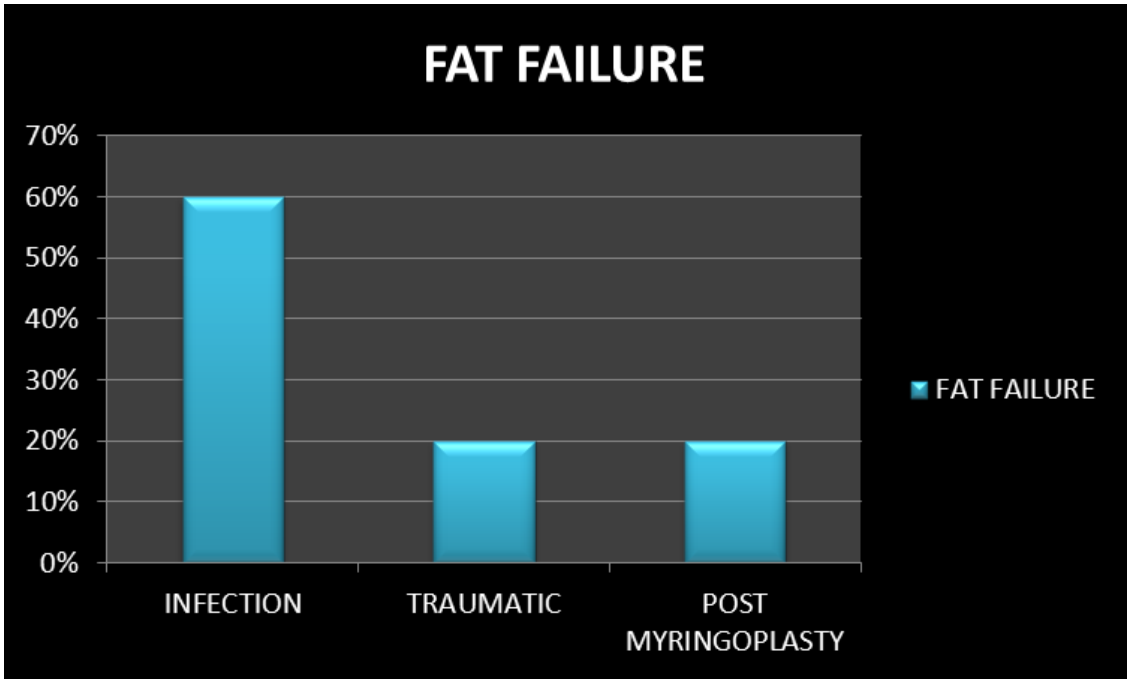
Procedure	Infection	Traumatic	Post myringoplasty
COLLAGEN SUCCESS	60%	80%	80%
FAT SUCCESS	78.60%	90.90%	80%

In both groups , Traumatic & post- myringoplasty cases have showed a higher success rate compared to Infective group.

FAILURE RATES IN EACH CAUSES







Procedure	Infection	Traumatic	Post myringoplasty
COLLAGEN FAILURE	40%	20%	20%
FAT FAILURE	60%	20%	20%

In our study , Infective causes have found to have more failure rates when compared to other causes .

Causes success-CROSSTABULATION				CAUSES			Total
				I	M	T	
Collagen		FAILURE	Count	6	1	2	9
			% within CAUSES	40.0%	20.0%	20.0%	30.0%
		SUCCESS	Count	9	4	8	21
			% within CAUSES	60.0%	80.0%	80.0%	70.0%
	Total		Count	15	5	10	30
			% within CAUSES	100.0 %	100.0 %	100.0 %	100.0 %
Fat		Failure	Count	3	1	1	5
			% within SUCCESS	60.0%	20.0%	20.0%	100.0 %
			% within CAUSES	21.4%	20.0%	9.1%	16.7%
		Success	Count	11	4	10	25
			% within CAUSES	78.6%	80.0%	90.9%	83.3%
	Total		Count	14	5	11	30
			% within CAUSES	100.0 %	100.0 %	100.0 %	100.0 %

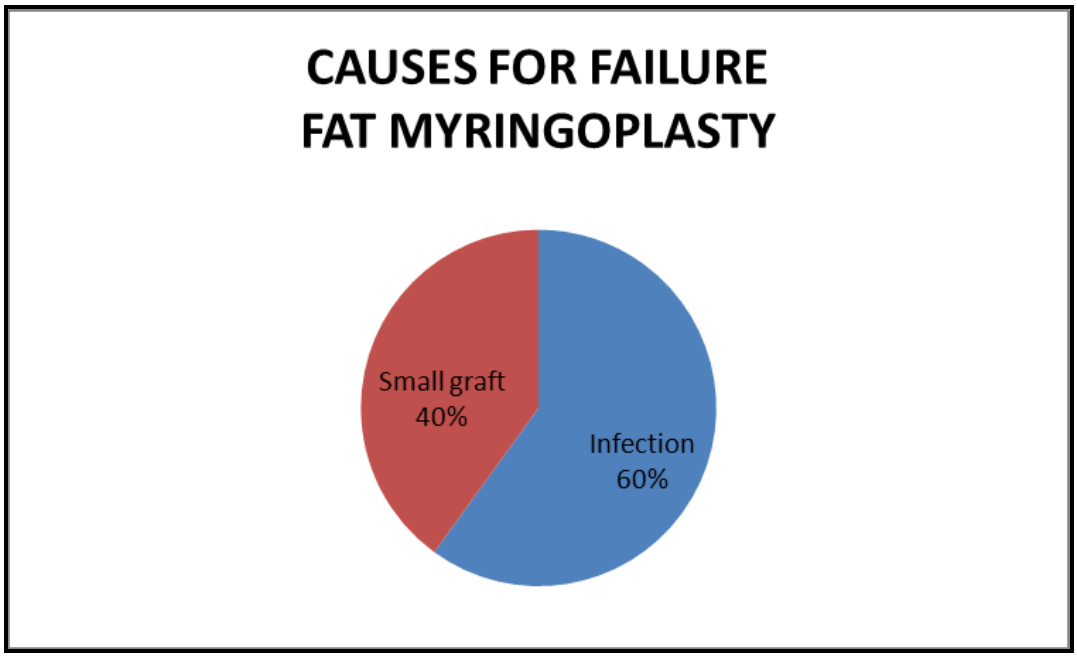
Collagen-CHI SQUARE -1.429

P value-0.484

Fat-CHI SQUARE-0.723

P value-0.677

CAUSES FOR FAILURE IN FAT MYRINGO GROUP

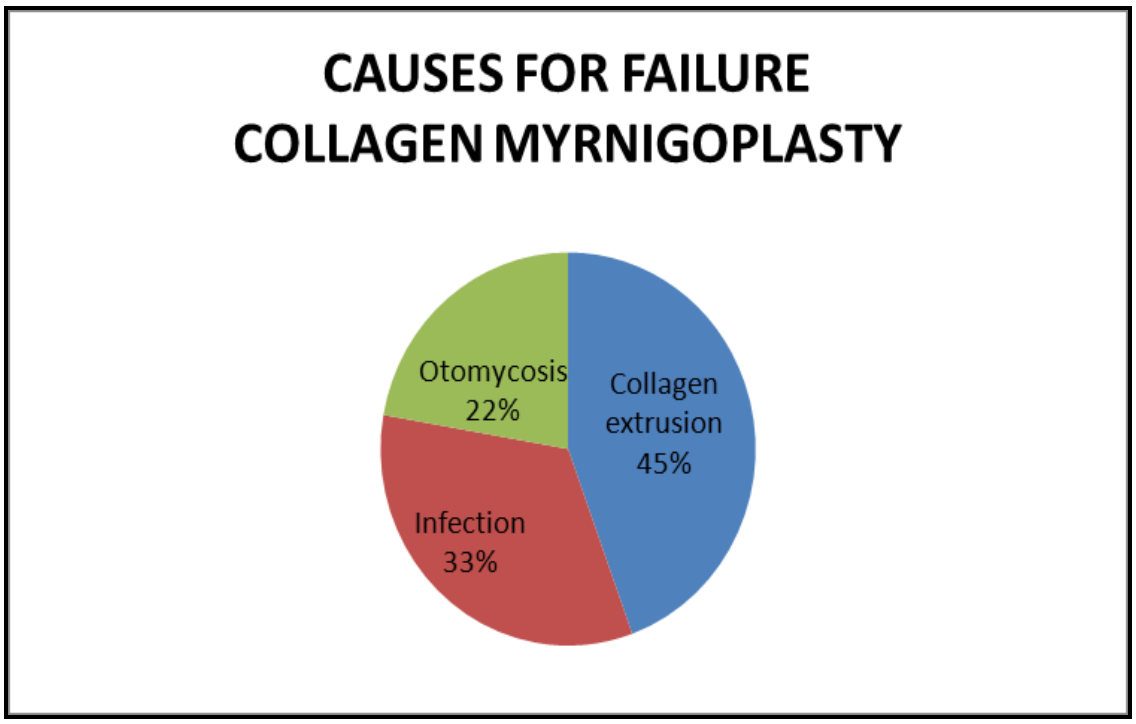


CAUSES FOR FAILURE IN FAT MYRINGOPLASTY

Causes for failure	No.of cases	Percentage
Infection	3	60%
Small graft	2	40%
Total	5	100%

In our study of 5 failure cases in fat plug technique, 60% were due to infective causes & 40% due to undersized fat graft.

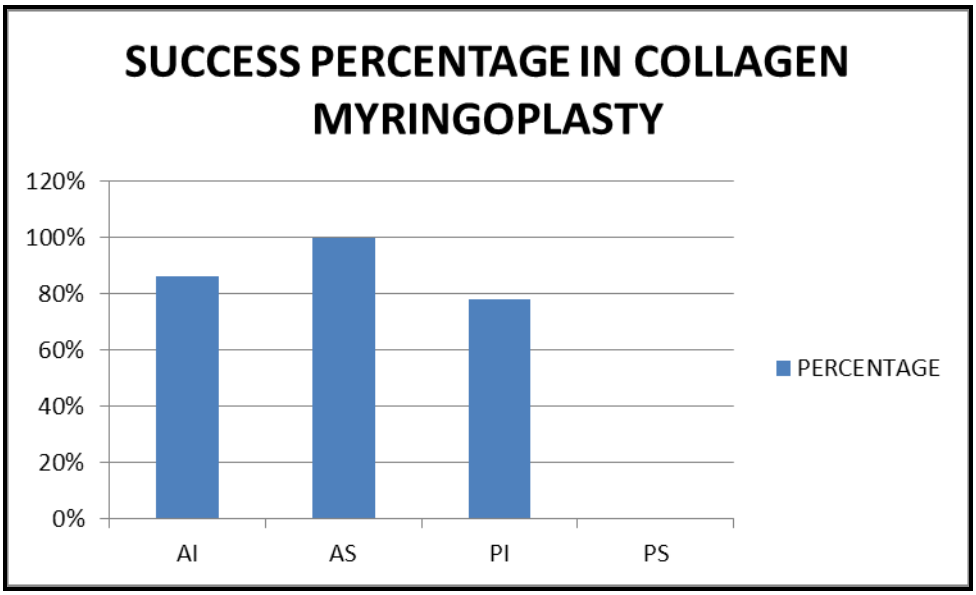
CAUSES OF COLLAGEN FAILURE



Causes for failure	No.of cases	Percentage
Collagen extrusion	4	44.44%
Infection	3	33.33%
Otomycosis	2	22.22%
Total	9	100%

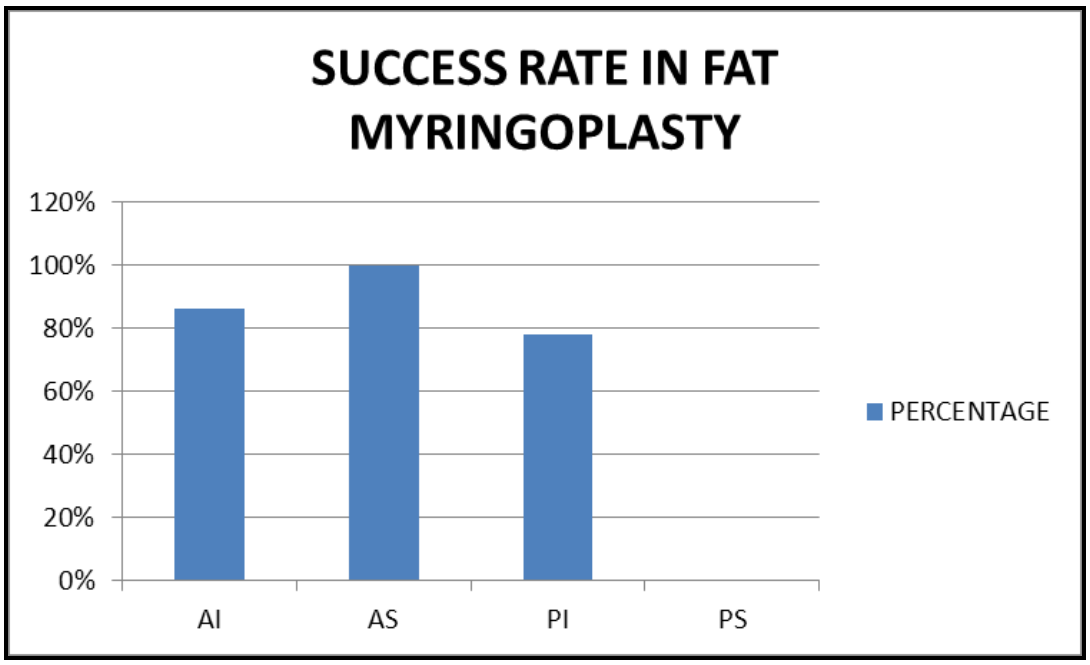
In our study , 44.4 % of failure cases were due to collagen extrusion compared to other causes.

SUCCESS PERCENTAGE AND QUADRANT COMPARISON



SUCCESS RATE OF EACH QUADRANT IN COLLAGEN MYRINGOPLASTY

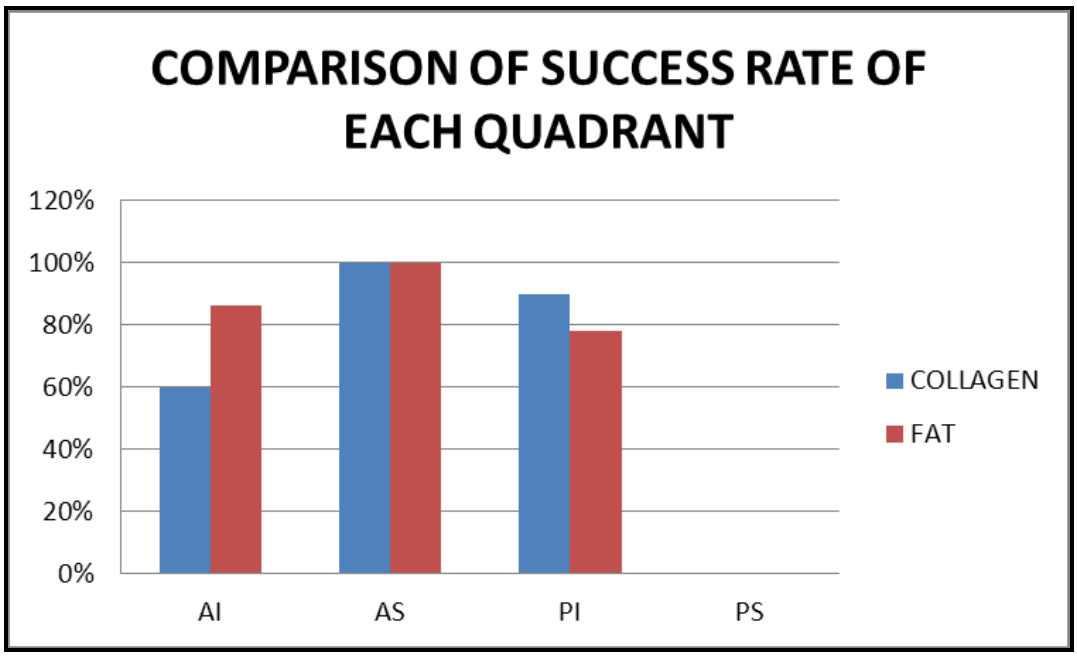
Quadrants	Total no.of patients	Success	Percentage
AI	15	9	60%
AS	3	3	100%
PI	10	9	90%
PS	2	0	0%



In our study , anterior quadrant perforations have found to have a higher success rates compared to posterior quadrant.

SUCCESS RATE OF EACH QUADRANT IN FAT MYRINGOPLASTY

Quadrants	Total no.of patients	Success	Percentage
AI	15	13	86%
AS	5	5	100%
PI	9	7	78%
PS	1	0	0%

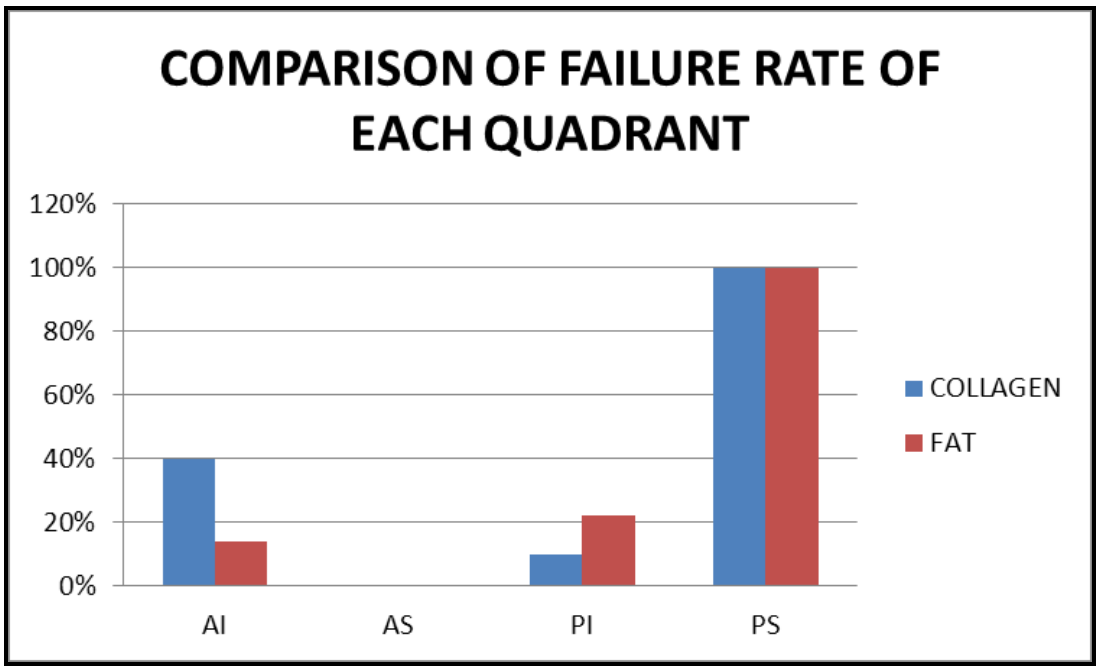


COMPARISON OF SUCCESS RATE OF EACH QUADRANT

Quadrants	Collagen	Fat
AI	60%	86%
AS	100%	100%
PI	90%	77.77%
PS	0%	0%

Anterior quadrant perforations have found to have a higher success rate compared to posterior quadrant. Postero-superior quadrant perforation had a least success rate.

FAILURE COMPARION & QUADRANT

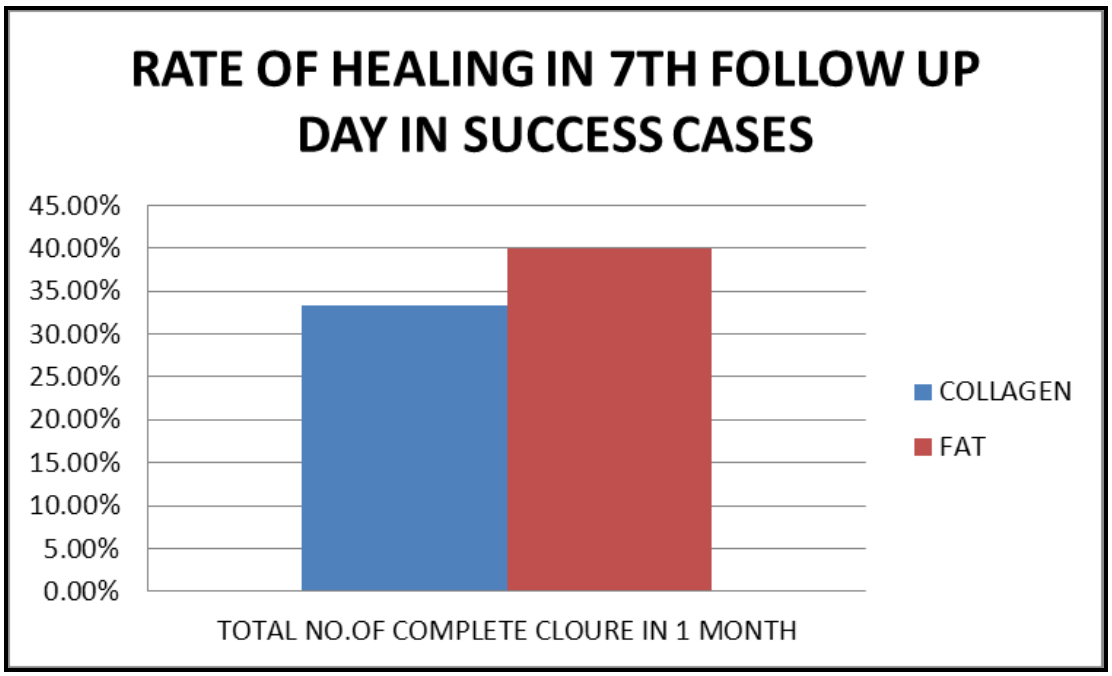


COMPARISON OF FAILURE RATE OF EACH QUADRANT

Failure rate of each quadrant	Collagen	Fat
AI	40%	14%
AS	0%	0%
PI	10%	22.23%
PS	100%	100%

Postero-superior quadrant perforations had comparatively more failure rates. & Antero-superior quadrant had least failure rate of all in our study groups.

COMPARISON OF RATE OF HEALING IN 7TH POST-OP DAY COLLAGEN VS FAT

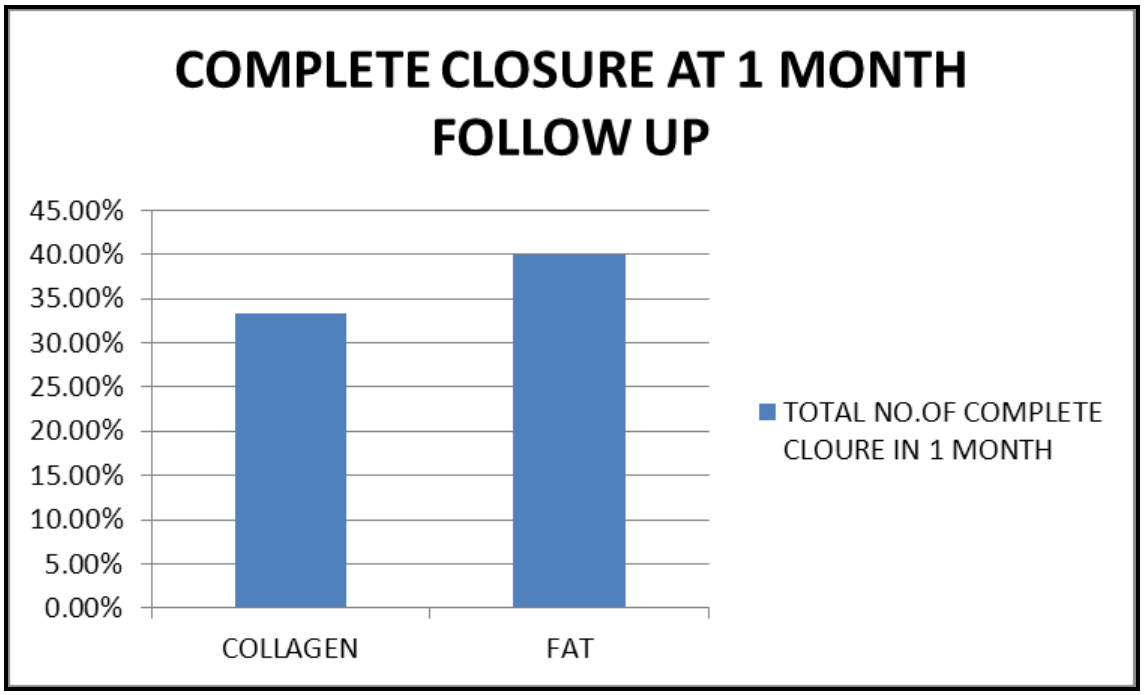


RATE OF HEALING IN 7TH FOLLOW UP DAY IN SUCCESS CASES

Procedure	Total no.of cases	Total no.of healed cases	Percentage
COLLAGEN	21	19	90.47%
FAT	25	20	80%

The study showed collagen cases had a comparatively (90.47%) faster onset of healing in 1st follow –up week.

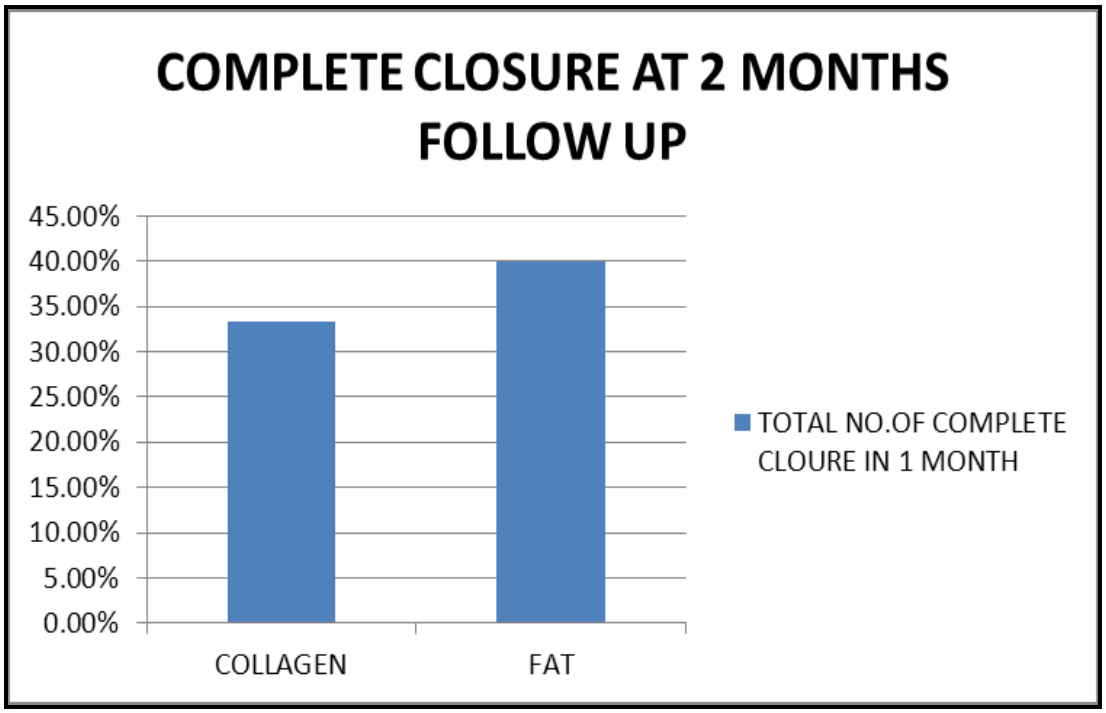
COMPLETE CLOSURE COMPARISON * 1 MONTH FOR COLLAGEN VS FAT



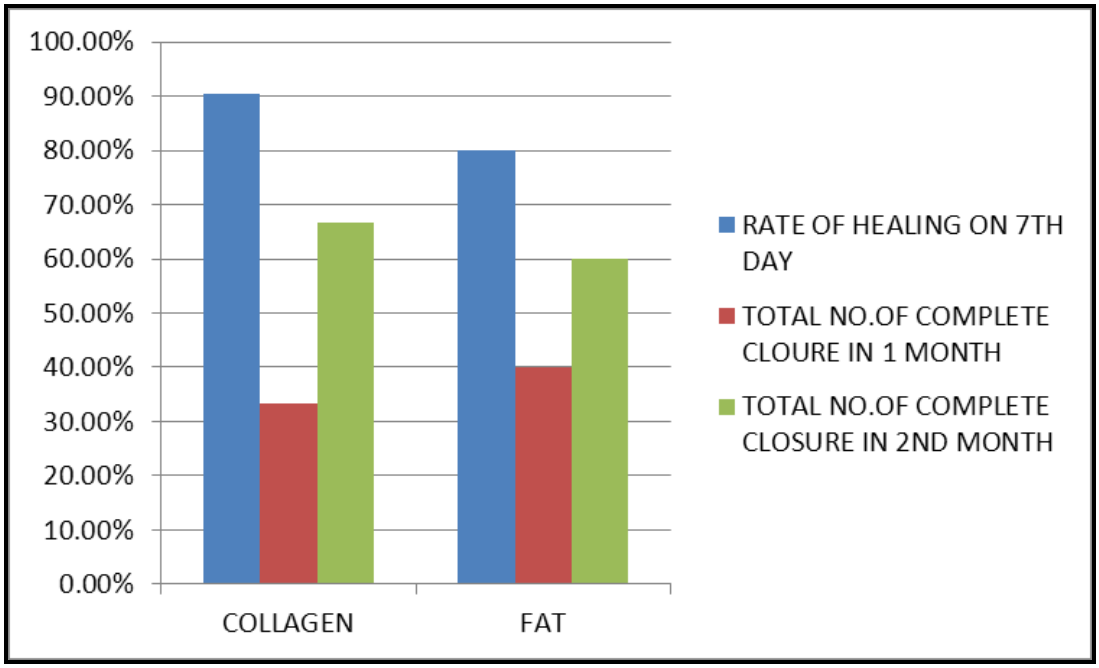
Procedure	Total no.of cases	Complete closure at 1 month follow up	Percentage
COLLAGEN	21	7	33.33%
FAT	25	10	40%

The study showed around 40% patients in fat had complete closure in 1st month compared to collagen 33.33%.

COMPARISON OF COMPLETE CLOSURE AT 2ND MONTH



Procedure	Total no.of cases	Complete closure at 2 months follow up	Percentage
COLLAGEN	21	14	66.66%
FAT	25	15	60%



Procedure	**Total no.of cases**	**Rate of healing on 7th day**	**Total no.of complete cloure in 1 month**	**Total no.of complete closure in 2nd month**
Collagen	21	90.47%	33.33%	66.66%
Fat	25	80%	40%	60%

The above charts & study showed that patients in Collagen group had a comparatively faster rate of healing at 7th day .Fat plug patients had a slightly increased percentage of complete closure at 1st month follow-up.

DISCUSSION

- The principal aim of our retrospective study is the complete closure of the small tympanic membrane perforations using a collagen patch and fat plug myringoplasty which are simple, short, cost effective office procedures.

- They have advantage of least pain and trauma to the healthy ear drum due to the absence of skin incisions, meatal flap dissections and fewer complications.

- These procedures also have an added advantage of maximum improvement of the air/bone gap after the procedure.

- Although fat plug myringoplasty and collagen patch are simple, safe and cost-effective procedures, they have been underused despite their numerous advantages.

- However, these office procedures cannot be always an alternative procedure to the conventional surgical myringoplasty in every tympanic membrane perforation.

- Certain clinical criteria should be applied and fulfilled for the perforation to have the highest possibility of these procedure's success.

- The clinical criteria established by Fiorino and Barbieri was used for the selection of patients eligible for these procedures .

- The first demonstration of fat plug myringoplasty was reported by **Ringenberg** in1962 where he showed success rate of 87%.
- In the following studies the success rate were shown to be ranging from 80% to 92% in cases of small perforations.
- **In this study, the success rate of the entire group of patients underwent fat plug myringoplasty 83.3%**
- Fat graft used in the cases with post tympanostomy tube extrusion with non-healing perforations showed 100% success rate in literature.
- Persistent TM perforations after chronic otitis media with tubotympanic disease and post traumatic causes showed 91% success rate after fat plug myringoplasty
- post myringoplasty patients with residual perforation showed 87.1% success rate.
- **In this study the rate of success for each aetiology were 78.6% for post-infection, 90.9% for post traumatic and 80% for post myringoplasty patients.**
- 17dB of mean improvement in A-B gap was recorded by **Saliba.**
- **Liew et al.,** recorded improvement in 11 out of 15 patients in their study;
- **Hagemann and Housler**, showed improvement in 21 out of 44 patients.

- **Fiorino and Barbieri** recorded a slight non-significant improvement in the A-B gap in 31 patients included in their study.

- **In this study, the mean improvement in the air/bone gap was 14dB at one month and 8.8dB at two months for the successful cases post operatively.**

- **The failure rate for this study was 16.7%**

- The causes for failures were noted in the literature to be due to infection, fat graft extrusion and and undersized grafts leading to dehiscence.

- In our study failures were noted to be due to infection and small sized grafts.

- **Fiorino and Barbieri** attributed the cause of immediate failures to be due to technical difficulties like anterior perforations, poor vascular supply, inadequate graft support and infection.

- Delayed failures were recorded due to infections, Eustachian tube dysfunction or tympanic membrane atrophy with the change in structure of tympanic membrane.

- **From failure cases (5 cases) we can observe that the failures were due to infection and small sized grafts.**

- These causes for failure rate would have been avoided if proper technique and if post procedure infections were controlled .

- In this study, the post myringoplasty residual perforation cases were operated upon after 6 months of failure of closure and the traumatic and the infective cases of perforation were operated upon after 3 months of complete dryness and failure of perforation closure.

THE ADVANTAGES OF FAT GRAFT INCLUDE

- Collapse of the grafts like in cases of underlay grafts especially at the area near the anterior annulus does not happen with Fat graft as it does not need support from the middle ear side.

- Fat graft remains undisplaced and remains in the same position

- Technical operative points during fat grafting such as “graft size in the perforation, degree of lateral bulge of the fat plug and moistening of the lateral side of the graft” are also considered to be important factors of success in the fat grafting procedure.

- Fat is an active material containing angiogenic and survival factors like prostaglandins, Monobutyrin, cytokines , interleukins 1 and 6 and tumour necrosis factor which stimulate restoration and repair of the fibrous layer and promote healing and there by closure of perforations.

- These factors also provide revascularization which is essential for survival of the free flap.

- Fat graft promotes growth factors including vascular endothelial growth factor, platelet derived growth factor, transforming growth factor beta, and fibroblast growth factor which promote the process of the tissue repair.

- " Fat contains high population of multipotent cells referred to as adipose-derived stem cells which are similar in activity to those of the bone marrow derived mesenchymal stem cells which has the ability to differentiate into mesenchymal tissues such as endothelial and fibrous types promoting the healing process of the tympanic membrane".

Total Success No.25 (83.3%)

Post traumatic -90.90%

Chronic tubotympanic inactive suppurative otitis media -78.6%

Post myringoplasty residual perforation -80%

Total Failure no.5(16.7%)

Post traumatic -20%

Chronic tubotympanic inactive suppurative otitis media -60%

Post myringoplasty residual perforation -20%

Factors behind failure of fat grafting among the operated ears.

Graft necrosis (due to postoperative infection)-3/5=60%

Undersized fat graft- 2/5=40%

Pre-and post-operative air-bone gap.

Air-bone gap (dB)

Preoperative mean-22dB

Postoperative mean-14dB at 1 month and 8.8dB at 2 month

Significance P<0.001 using ANOVA TEST

Down the century many auto and allografts like fascia, vein grafts, fat, skin, perichondrium, cartilage and Alloderm have been tried with varying success rates.

Each graft has their own advantages and disadvantages.

Many xenografts and synthetic graft materials like paper patch, gelfoam plug and grafts of hyaluronic acid derivatives have been studied.

Commercially available xenografts like porcine small intestine submucosa have also been tried.

Recently many studies have been done using biomaterials such as silk fibroin, calcium alginate and chitosan.

Collagen which is the component of TM and are found in extracellular matrix have also been tried.

Unfortunately only limited studies have been carried out using collagen as the graft material.

Collagen scaffolds have been used as the graft material in rats and have proven to be effective.

Collagen-immobilized patch have been analyzed and it showed 70% success rate which was comparatively equivalent to other biomaterials.

ADVANTAGES OF COLLAGEN AS GRAFT

- Collagen is one of the major components of extracellular matrix which has some important physical properties that aid in healing of TM perforations.
- It has high tensile strength
- Flexibility is an important property which helps in maintaining the physiology of tympanic membrane
- It also has other important properties like non-toxicity, non-reactivity and non-carcinogenicity.
- Tympanic membrane normally said to contain collagen type I,II,III,IV,VI in its lamina propria layer.
- Collagen helps in maintaining the intergrity and resilience of the tympanic membrane which is important in maintaining the physiological functions of normal TM.
- Since collagen is the constituent of the normal TM and it promotes the healing factors, collagen when used as the graft material promotes healing.
- Allows the patient's fibroblasts to grow and proliferate on the graft.
- Attachment of the fibroblast cells was facilitated by the collagen
- It has good manipulation properties,
- Collagen easily adheres to the TM surface

- Collagen grafts are fully transparent and hence the margins of the perforations can be easily seen by the surgeons.
- It also facilitates monitoring of the post procedure events due to its transparency.
- Previous studies showed that by day 7, there appears a thick, opaque newer healing margin with lots of micro-vessels. By day 14 the tympanic membrane showed to be more transparent and most of the perforations were closed. At 28^{th} day all the perforations in the success rate were completely closed.
- In our study the healing of the TM perforation started as early as day 7.
- Some cases showed the appearance of healing TM only after 2weeks
- The complete closure of the perforation in cases that were included in success rates were first noted by day 30.
- Remaining patients showed complete closure by day 60.
- In our case study we had 21 out of 30 patients in success category
- We had failure of perforation closure in 9 patients.
- The causes for the failure of closure were attributed to presence of infection, otomycosis and collagen patch extrusion.
- In literature the causes of failure rate was mainly due to fungal otitis externa, collagen extrusion, URI with Eustachian tube dysfunction, and unknown cause of otorrhoea.

- In this study, success rate was found to be 70% & failure rate was 30 %
- The mean improvement in the air/bone gap was 14.33db at 1 month and 7.97db at 2 months for the successful cases post operatively.

Total Success no.-21 (70%)

Post traumatic -80%

Chronic tubotympanic inactive suppurative otitis media -60%

Post myringoplasty residual perforation -80%

Total Failure no.-9(30%)

Post traumatic -20%

Chronic tubotympanic inactive suppurative otitis media -40%

Post myringoplasty residual perforation -20%

Factors behind failure of collagen patch technique among the operated ears.

Collagen extrusion-4/9=44.4%

Infection-3/9=33.3%

Otomycosis-2/9=22.2%

Pre-and post-operative air-bone gap.

Air-bone gap (dB)

Preoperative mean-21.8db

Postoperative mean-14.3db at 1 month and 7.9db at 2 months

Significance P<0.001 using ANOVA TEST

COMPARISON

- Rate of healing (days)
- PTA - improvement in air bone gap
- Complications with the procedure
- Patient compliance
- Structure of TM – uniform thickness or opaque..
- further sub classify Healing rates compared to etiology
- Failure causes

BENEFITS TO THE COMMUNITY

1) Awareness of various treatment modalities

2) Awareness about the ill effects of small perforations & management by office procedures.

3) Procedure time was less than 20 Mts and hence the reduction in required hospital stay

4) 4. As the only performed procedure was freshening of the perforation margin, there was no pain for the patients.

CONCLUSION

In this prospective study of 60 patients with small tympanic membrane perforations, we have **compared newer biomaterial collagen patch and conventional fat plug as a office procedure in treatment** .

According to our study , both groups had a significantly equal **success rates and the rate of healing and complete closure at the end of 1 & 2 months follow up were also almost equal in both groups.**

The hearing improvement in A-B gap during follow up of both groups were compared with pre-operative Air Bone gap and this showed that both collagen patch & fat plug groups had **a significant improvement in hearing** following procedure.

In our study quadrant of perforation does not correlate with the amount of hearing & healing rates were comparatively better in anterior quadrant than posterior quadrant.

Infective causes were found to be more & the failure rates were also high for such cause in both groups.

No complications have been encountered in the study and the patient compliance was comparatively better when compared to myringoplasty , as it is less traumatic and time consuming.

Collagen patch technique is incisionless so less painful and cosmetically better when compared to fat plug myringoplasty

The main aim of our study is to evaluate the role and efficacy of office procedures in closure of small perforations and thus reducing the complications.

Of the various graft materials tried in the literature, newer biomaterials like collagen & fat plug can also be used for closure of perforations with a significantly better results.

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ABBREVIATIONS

TM	:	Tympanic Membrane
EAC	:	External Auditory Canal
A-B	:	Air Bone
dB	:	Decibel
AI	:	Anteroinferior
AS	:	Anterosuperior
PI	:	Posteroinferior
PS	:	Posterosuperior

PROFORMA

1. Name :
2. Age :
3. Sex :
4. Standard :
5. Hospital No :
6. Occupation :
7. Address :
8. Contact No :

Previous history of..	Yes	No
Ear discharge		
Hard of hearing		
Tinnitus		
Vertigo with or without Aura		
Previous surgery		
History of trauma		

9. Examination
    a. General examination
        i. Level of consciousness
        ii. Vital signs
            1. Pulse
            2. Blood pressure
            3. Respiratory rate
            4. Temperature
    b. Systemic examination
        i. Respiratory system
        ii. cardiovascular system
        iii. central nervous system
        iv. per abdomen

c. ENT examination

i. Ear

Part	**Right**	**Left**
Pinna		
Pre-auricular region		
Post auricular region		
External auditory canal		
Tympanic membrane • Perforation • Other findings		

10. Tuning Fork Test

11. Vestibular Function Test (Romberg and Unterberger)

12. Examination of Nose

13. Examination of Throat

Audiological Test

	Right ear	**Left ear**
PTA		

`S.NO	NAME	AGE	SEX	SIDE OF PERFORATION	PERFORATION QUADRANT	POST INFECTIVE	POST TRAUMATIC	POST MYRINGO PLASTY	INITIAL A-B GAP (dB)	7th DAY FOLLOW UP	14th DAY FOLLOW UP	1st MONTH FOLLOW UP	2nd MONTH FOLLOW UP	A-B GAP AT 1 MONTH (dB)	A-B GAP AT 2 MONTHS (dB)	SUCCESS/ FAILURE	CAUSE FOR FAILURE	COMPLICATIONS IF ANY
1	PRABAKAR	42	M	LEFT	A.I			✓	25	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	18	10	SUCCESS		NIL
2	RAKESH KUMAR	24	M	LEFT	A.I		✓		22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	16	8	SUCCESS		NIL
3	AMAR	23	M	LEFT	P.I		✓		20	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	15	6	SUCCESS		NIL
4	SANTHAKUMARI	36	F	RIGHT	P.I	✓			24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	12	8	SUCCESS		NIL
5	PINKYSINGH	37	F	LEFT	A.I	✓			18	-	-	HEALING STARTED	COMPLETE CLOSURE	12	6	SUCCESS		NIL
6	GOWRI	36	F	LEFT	P.I	✓			24	-	-	HEALING STARTED	INCOMPLETE CLOSURE	20	14	FAILURE	INFECTION	NIL
7	INDRANI	42	F	RIGHT	A.S	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	15	8	SUCCESS		NIL
8	SHARMILA	18	F	RIGHT	A.I		✓		22	-	-	-	INCOMPLETE CLOSURE	18	6	FAILURE	COLLAGEN EXTRUSION	NIL
9	SUSEELA	38	F	LEFT	A.S	✓			24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	16	10	SUCCESS		NIL
10	SARANYA	16	F	LEFT	P.S		✓		18	-	-	-	INCOMPLETE CLOSURE	12	8	FAILURE	COLLAGEN EXTRUSION	NIL
11	SARALA	48	F	LEFT	P.I		✓		22	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	16	12	SUCCESS		NIL
12	KARTHIK	27	M	RIGHT	A.I	✓			18	-	HEALING STARTED	ONGOING HEALING	INCOMPLETE CLOSURE	10	6	FAILURE	INFECTION	NIL
13	VIJAYAKUMARI	41	F	RIGHT	A.I	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	6	SUCCESS		NIL
14	MANJU	35	F	LEFT	P.I		✓		26	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	18	8	SUCCESS		NIL
15	ILAVARASI	19	F	RIGHT	P.I	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	6	SUCCESS		NIL
16	JAYAVEERARAJAN	36	M	LEFT	P.I		✓		22	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	14	6	SUCCESS		NIL
17	SURESH	28	M	RIGHT	A.I	✓			22		HEALING STARTED	ONGOING HEALING	INCOMPLETE CLOSURE	16	8	FAILURE	INFECTION	NIL
18	REVATHY	27	F	LEFT	A.I		✓		24	HEALING STARTED			COMPLETE CLOSURE	16	12	SUCCESS		NIL
19	UMA	36	F	RIGHT	A.I	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	12	6	SUCCESS		NIL
20	MURUGAN	41	M	RIGHT	A.I			✓	18	-	-	HEALING STARTED	INCOMPLETE CLOSURE	12	8	FAILURE	COLLAGEN EXTRUSION	NIL
21	SRINIVASAN	27	M	LEFT	A.I			✓	23	-	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	14	8	SUCCESS		NIL
22	URMILA	32	F	LEFT	P.I			✓	22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	18	14	SUCCESS		NIL
23	SWATHI	24	F	LEFT	A.I	✓			20	-	HEALING STARTED	ONGOING HEALING	INCOMPLETE CLOSURE	14	8	FAILURE	OTOMYCOSIS	NIL
24	RUBINI	22	F	RIGHT	P.I	✓			22	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	16	8	SUCCESS		NIL
25	KOWSIYA	42	F	LEFT	A.I	✓			22	-	-	-	INCOMPLETE CLOSURE	12	6	FAILURE	COLLAGEN EXTRUSION	NIL
26	RAJENDRAN	44	M	RIGHT	A.I		✓		24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	8	SUCCESS		NIL
27	RAJAKUMARAN	50	M	RIGHT	P.I		✓		26	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	14	8	SUCCESS		NIL
28	SHANMUGAM	48	M	RIGHT	A.I	✓			22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	10	5	SUCCESS		NIL
29	VALARMATHI	41	F	RIGHT	A.S			✓	20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	10	6	SUCCESS		NIL
30	MOHANA	29	F	LEFT	P.S	✓			24	-	HEALING STARTED	ONGOING HEALING	INCOMPLETE CLOSURE	12	6	FAILURE	OTOMYCOSIS	NIL

S.NO	NAME	AGE	SEX	SIDE OF PERFORATION	PERFORATION QUADRANT	POST INFECTIVE	POST TRAUMATIC	POST MYRINGO PLASTY	INITIAL A-B GAP (dB)	7th DAY FOLLOW UP	14th DAY FOLLOW UP	1st MONTH FOLLOW UP	2nd MONTH FOLLOW UP	A-B GAP AT 1 MONTH (dB)	A-B GAP AT 2 MONTHS (dB)	SUCCESS/ FAILURE	CAUSE FOR FAILURE	COMPLICATIONS IF ANY
1	VENKATAIAH	42	M	LEFT	A.I	✓			24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	6	SUCCESS		NIL
2	PARVATHY	36	F	LEFT	A.I		✓		22	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	14	8	SUCCESS		NIL
3	MANJULA	45	F	RIGHT	P.I	✓			22	-	-	-	INCOMPLETE CLOSURE	20	16	FAILURE	SMALL GRAFT SIZE	NIL
4	RAMU	48	M	RIGHT	P.I	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	10	SUCCESS		NIL
5	SUNDAR	34	M	LEFT	A.I		✓		19	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	12	7	SUCCESS		NIL
6	SELVAM	33	M	LEFT	A.S	✓			26	-	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	12	8	SUCCESS		NIL
7	VIJAYA	29	F	LEFT	A.I			✓	20	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	10	8	SUCCESS		NIL
8	LATHA	45	F	RIGHT	A.I	✓			20	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	12	8	SUCCESS		NIL
9	SANKAR	39	M	RIGHT	P.I		✓		24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	12	SUCCESS		NIL
10	INDRA	49	F	LEFT	A.S		✓		22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	15	6	SUCCESS		NIL
11	LAKSHMI	38	F	RIGHT	A.I	✓			22	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	14	8	SUCCESS		NIL
12	SUNDARI	42	F	LEFT	P.I			✓	18	-	--	HEALING STARTED	INCOMPLETE CLOSURE	15	14	FAILURE	INFECTION	NIL
13	RAMESH	27	M	LEFT	A.S	✓			19	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	12	6	SUCCESS		NIL
14	KALA	32	F	RIGHT	A.I		✓		22	-	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	12	6	SUCCESS		NIL
15	SUMATHI	40	F	LEFT	A.I		✓		26	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	8	SUCCESS		NIL
16	RAVI	26	M	RIGHT	A.I	✓			28	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	6	SUCCESS		NIL
17	JOTHI	34	F	LEFT	P.I	✓			24	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	16	12	SUCCESS		NIL
18	PRIYA	24	F	RIGHT	P.I		✓		22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	6	SUCCESS		NIL
19	UMA	30	F	LEFT	A.I			✓	24	-	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	12	7	SUCCESS		NIL
20	RANJANI	27	F	LEFT	P.S	✓			24	-	-	-	INCOMPLETE CLOSURE	20	16	FAILURE	INFECTION	NIL
21	THIYAGU	40	M	RIGHT	A.I	✓			20	-	HEALING STARTED	COMPLETE CLOSURE	HEALED CP +	12	6	SUCCESS		NIL
22	RANI	38	F	LEFT	P.I			✓	22	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	8	SUCCESS		NIL
23	RAJU	41	M	LEFT	A.S		✓		18	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	12	5	SUCCESS		NIL
24	SHANTHY	40	F	RIGHT	A.I		✓		20	-	-	-	INCOMPLETE CLOSURE	20	20	FAILURE	SMALL GRAFT SIZE	NIL
25	FOUSIYA BEGUM	42	F	LEFT	P.I	✓			20	-	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	10	2	SUCCESS		NIL
26	GAYATHRI	29	F	RIGHT	A.S		✓		20	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	10	4	SUCCESS		NIL
27	GANESH	28	M	LEFT	A.I	✓			26	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	12	6	SUCCESS		NIL
28	SUMITHA	33	F	LEFT	P.I			✓	20	HEALING STARTED	ONGOING HEALING	COMPLETE CLOSURE	HEALED CP +	16	7	SUCCESS		NIL
29	RAFFIQ	43	M	RIGHT	A.I	✓			22	-	-	-	INCOMPLETE CLOSURE	20	18	FAILURE	INFECTION	NIL
30	HEPSI FREEDA	27	F	LEFT	A.I		✓		24	HEALING STARTED	ONGOING HEALING	ONGOING HEALING	COMPLETE CLOSURE	14	10	SUCCESS		NIL

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.M.Ajaiy
Postgraduate M.S.(ENT)
Madras Medical College
Chennai 600 003

Dear Dr.M.Ajaiy,

The Institutional Ethics Committee has considered your request and approved your study titled **"A comparative study of using collagen patch or fat plug in myringoplasty for small tympanic membrane perforations" No.11032015.**

The following members of Ethics Committee were present in the meeting held on 03.03.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC	: Member
7. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
8. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
9. Prof.S.G.Sivachidambaram, M.D.,Director i/c Institute of Internal Medicine, MMC, Ch-3	: Member
10. Thiru S.Rameshkumar, B.Com., MBA	: Lay Person
11. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
12. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

INFORMATION SHEET

We are conducting a prospective cohort study on **" A COMPARATIVE STUDY OF USING COLLAGEN PATCH OR FAT PLUG IN MYRINGOPLASTY FOR SMALL TYMPANIC MEMBRANE PERFORATIONS "** at the Upgraded Institute of Otorhinolaryngology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 600003

- These collagen patch technique & fat plug techniques are done as office procedures, so patient needs less hospital stay.
- At the time of announcing the results and suggestions, name and identity of the patients will be confidential.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator **Signature of Participant**

Date :

PATIENT CONSENT FORM

Title of the Project : " A COMPARATIVE STUDY OF USING COLLAGEN PATCH OR FAT PLUG IN MYRINGOPLASTY FOR SMALL TYMPANIC MEMBRANE PERFORATIONS "

Institution : Upgraded Institute of Otorhinolaryngology,
Madras Medical College,
Chennai – 600003.

Name :

Date :

Age :

IP No. :

Sex :

Project Patient No. :

The details of the study have been provided to me in writing and explained to me in my own language.

I confirm that I have understood the above study and had the opportunity to ask questions.

I understood that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I have been given an information sheet giving details of the study.

I fully consent to participate in the above study.

_____	_____	_____
Name of the subject	Signature	Date
_____	_____	_____
Name of the Investigator	Signature	Date

ஆராய்ச்சி தகவல் தாள்

பல்வேறு காரணங்களினால் நமது காதின் நடுப்பகுதியில் ஓட்டை ஏற்படுகிறது. இதனை நம்மில் பலர் அலட்சியமாக எடுத்துக்கொள்கின்றனர். இந்த ஓட்டை சிறியதாக இருந்தாலும், அதனால் நமது உள் காது மற்றும் மூளைப்பகுதியில் பல்வேறு பாதிப்புகள் ஏற்பட வாய்ப்புள்ளது.

இந் நோயை குணப்படுத்த பல்வேறு அறுவை சிகிச்சைகள் நமது இராஜீவ் காந்தி அரசு பொது மருத்துவமனையில் நடத்தப்பட்டு வருகின்றன. எனினும் அறுவை சிகிச்சையினால் நீண்ட நாட்கள் மருத்துவமனையில் தங்க வேண்டியிருக்கும் என்று பலரும் இதனை தவிர்க்கின்றனர். இந்த ஆராய்ச்சியின் மூலம் **"கொலோசென்" அல்லது "கொழுப்பு "** கொண்டு இதனை குணப்படுத்த வாய்ப்புள்ளது. இதனால் நோயாளி ஒரு சில மணிநேரத்திலேயே வீட்டிற்கு சென்று விடலாம். இதனால் ஏற்படும் வலியும் குறைவாக இருக்கும்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ, அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ, அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதை தெரிவித்துக்கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில்தான் இருக்கிறது. மேலும் நீங்கள் எந்த நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின்வாங்கலாம் என்பதைத்தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்பு பரிசோதனைகளின் முடிவுகளையும் நோயின் தன்மை பற்றியும் ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

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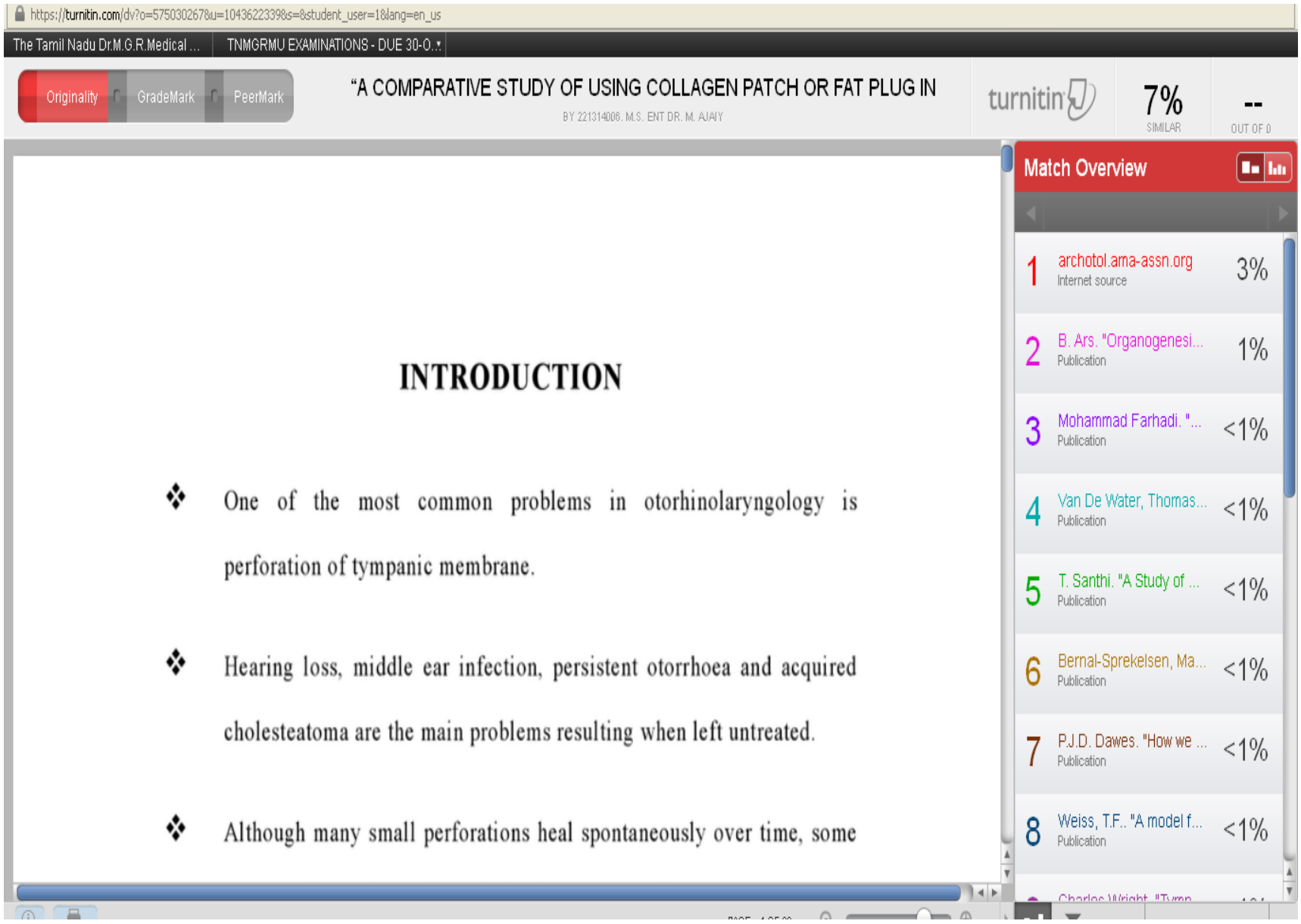
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One of the most common problems in otorhinolaryngology is perforation of tympanic membrane.
Hearing loss, middle ear infection, persistent otorrhoea and acquired cholesteatoma are the main problems resulting when left untreated.
Although many small perforations heal spontaneously over time, some
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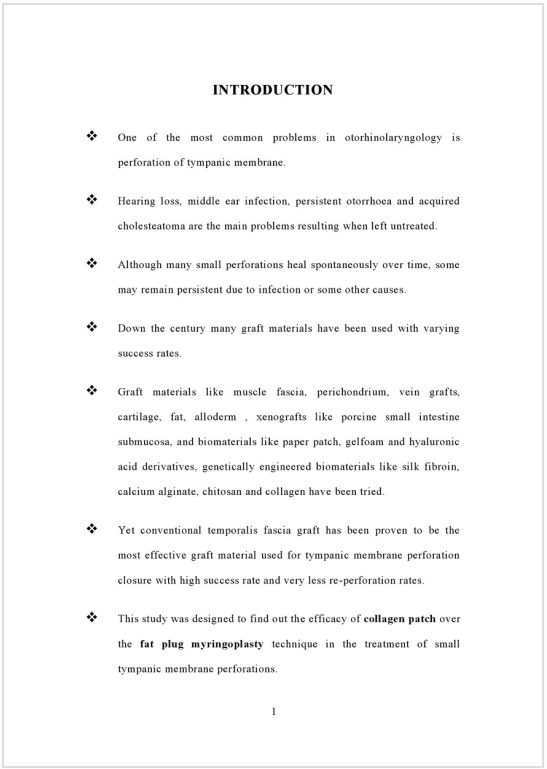

INTRODUCTION

- One of the most common problems in otorhinolaryngology is perforation of tympanic membrane.
- Hearing loss, middle ear infection, persistent otorrhoea and acquired cholesteatoma are the main problems resulting when left untreated.
- Although many small perforations heal spontaneously over time, some may remain persistent due to infection or some other causes.
- Down the century many graft materials have been used with varying success rates.
- Graft materials like muscle fascia, perichondrium, vein grafts, cartilage, fat, alloderm , xenografts like porcine small intestine submucosa, and biomaterials like paper patch, gelfoam and hyaluronic acid derivatives, genetically engineered biomaterials like silk fibroin, calcium alginate, chitosan and collagen have been tried.
- Yet conventional temporalis fascia graft has been proven to be the most effective graft material used for tympanic membrane perforation closure with high success rate and very less re-perforation rates.
- This study was designed to find out the efficacy of **collagen patch** over the **fat plug myringoplasty** technique in the treatment of small tympanic membrane perforations.

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